



University of
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No Need(le) To Worry: development and feasibility
study of a self-help cognitive behavioural therapy
resource for children with needle fear

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requirements for the degree of Doctor of Philosophy

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To the only man I'd marry twice - Te iubesc până la lună și înapoi.

Dissemination

Website



If the above no longer works (correct as of 22/01/2025) the most up to date website link can be found at:

<https://www.sheffield.ac.uk/dentalschool/our-people/academic-staff/fiona-sotir>

Papers

1. **Protocol paper**

'Protocol for a feasibility study of a self-help resource based on the principles of cognitive behavioural therapy to reduce needle fear in adolescents aged 11 - 16 years'

Fiona Sotir, David White, Gemma Wheeler, Helen Rodd and Zoe Marshman

BMC Pilot and Feasibility Studies

Under review

2. **PhD report**

'No Need(le) To Worry: Co-design of a self-help cognitive behavioural therapy resource for young people with needle fear'

Fiona Sotir

The Design Journal

Under review

Presentations and publications

Presentations

Oral presentations

1. 'Management of children's needle fear: a rapid review'
Research Prize Category
British Society of Paediatric Dentistry Conference
Sheffield, United Kingdom
September 2022
2. 'Blending health and design: co-design in dentistry'
Young Researcher category
International Association of Paediatric Dentistry Conference
Maastricht, Netherlands
June 2023
3. 'No Need(le) To Worry – developing a PhD project'
Online webinar
CONNECT research group
United Kingdom
July 2023
4. 'No Need(le) To Worry – managing paediatric needle fear'
Online webinar
BSPD Northeast branch
United Kingdom
March 2024
5. 'No Need(le) To Worry – developing a resource for young people with needle fear'
Invited speaker
BSPD Merseyside branch spring study day
Liverpool, United Kingdom
April 2024

6. 'No Need(le) To Worry – a resource for young people with needle fear'
Invited speaker
BSPD West and East of Scotland joint study day
Glasgow, United Kingdom
June 2024

7. 'Blending health and design: a resource for young people with needle fear'
Research Prize Category (winner)
British Society of Paediatric Dentistry Conference
Cardiff, United Kingdom
September 2024

Poster presentations

1. 'A self-help resource for young people with needle fear'
Poster Presentation
British Association of Community Child Health
Glasgow, United Kingdom
October 2024

Abstract

Background

The aim of this thesis was to develop and conduct a feasibility study of a self-help tool, based on the principles of cognitive behavioural therapy, for young people aged 11-16 years old with needle fear. Young people with fear of needles have been managed with many different techniques, but none of these have been developed specifically *for* or *with* young people, and the evidence for their effectiveness is limited.

Methods

This study was undertaken in three stages.

Stage one involved qualitative interviews to explore the experiences and impacts of needle fear, and preferences for a self-help resource, of young people and their parent/carers.

Stage two utilised a co-design approach to develop the resource *with* young people, parent/carers and healthcare professionals.

Stage three was a mixed methods uncontrolled feasibility study of a protocol to test the effectiveness of the resource in future.

Results

The key findings were:

Stage one

1. We found that young people want control over their healthcare experiences
2. Young people have worries about how their needle fear might impact them in the future
3. Interactions and relationships with adults (parents and healthcare professionals) could be important in framing young people's experiences

4. An online resource was preferred, which would contain information about common needle-based procedures, coping strategies, and a tool to support communication about worries with healthcare professionals
5. Parents indicated a need for a parent resource to help them support their children

Stage two

1. Young people, parents, and healthcare professionals can be effectively engaged as collaborators through a co-design approach
2. Co-design activities worked effectively in both face-to-face and online settings
3. The co-design collaboration designed a website resource containing all the requested content, and a communication tool to help young people use writing to communicate their worries to their healthcare professional
4. The resource is also accessible offline and has supporting audio files to ensure it is more inclusive.

Stage three

5. All planned settings (100%) were recruited to the study, although there were challenges in recruiting the school setting
6. Participants were able to be recruited from each setting, but amendments are recommended to improve recruitment rates in future work
7. The completion rate was 40.9%
8. Healthcare professionals are willing to recruit to future randomised studies
9. Young people and parents in this study are willing to be recruited to future studies, although further work should be undertaken to determine if this is acceptable to a larger population
10. The resource is acceptable to the young people, parents, and healthcare professionals in this study, although further work should be undertaken to determine if it is acceptable to a larger population

Conclusion

The study highlighted some alterations that could be made to the protocol and some key uncertainties that should be addressed prior to definitive evaluation of the resource.

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Abbreviations

ADHD	Attention-Deficit Hyperactivity Disorder
APA	American Psychological Association
ATT	Applied Tension Technique
ART	Applied Relaxation Technique
BAT	Behavioural Avoidance Test
BII	Blood-Injection-Injury phobia
BS	Ball Squeezing
CAM	Child Anxiety Meter
CAMHS	Child and Adolescent Mental Health Service
CAPS	Children's Anxiety and Pain Scale
CASS	Children's Anxiety Scale - State
CARL	Computer Assisted Relaxation Learning
CBT	Cognitive Behavioural Therapy
CFS	Children's Fear Scale
CFSS-DS	Children's Fear Survey Schedule-Dental Subscale
DFIQ	Dialysis Fear of Injection Questionnaire
D-FISQ	Diabetes Fear of Injecting and Self-testing Questionnaire
DFS	Dental Fear Survey
DW	Mr David White (Research Supervisor)
EBCD	Experience-Based Co-Design
EIV	Exposure In Vivo
FS	Mrs Fiona Sotir (PhD student)
GW	Dr Gemma Wheeler (Research Supervisor)
HCP	Healthcare Professional
HPV	Human Papilloma Virus
HST	Helpfor Skin Tap
HR	Professor Helen Rodd (Research Supervisor)
IOIF-s	Intra-oral Injection Fear Scale
IPS-Anx	Injection Phobia Scale
IPS-Anx-C	Injection Phobia Scale Child version
IPS-SF	Injection Phobia Scale Anxiety Short Form
ISAR	Interval Scale of Anxiety Response
ISSR	Immunisation Stress Related Responses
IVR	Immersive Virtual Reality
KD	Ms Katy D'Apice (Research Nurse)
KR	Katie Rawlins (Graphic Designer)
MCDAS	Modified Children's Dental Anxiety Scale
MDAS	Modified Dental Anxiety Scale

MTD	Message to Dentist
NBP	Needle Based Procedure
NHS	National Health Service
NIHR	National Institute for Health and Care Research
NS	Needle Survey
OC	Online Cohort
ONS	Office of National Statistics
OSBA	Observation Scale of Behavioural Distress
PCORI	Patient-Centred Outcomes Research Institute
PPI	Patient and Public Involvement
PW	Dr Polly Waite (Lecturer in Clinical Psychology)
RCMAS	Revised Children's Manifest Anxiety Scale
RCT	Randomised Controlled Trial
SBB	Soap Bubble Blowing
SBR	ShotBlocker®
SIAC	Self Injection Assessment Questionnaire
STAIC	State-Trait Anxiety Inventory for Children
TH	Theo Hayne (Graphic Designer)
TO	Tension Only
VAA-R	Visual Analog Scale for Anxiety – Revised
VAS	Visual Analog Scale
VR	Virtual Reality
VRSS	Verbal Rating Scale Stress
YO	Years old
ZM	Professor Zoe Marshman (Research Supervisor)

Chapter One

1. Introduction

1.1 Background

Fear of needles is a common issue worldwide, with the most recent estimated global prevalence of 50% in children and adolescents (McLenon and Rogers, 2019). The term 'needle fear' is used throughout this thesis to describe anxiety around needles, although it is acknowledged that there are discrete differences between fear and anxiety, and that fear exists on a spectrum from mild through to phobia. The phrase 'needle' relates to any form of healthcare procedure where a needle is utilised such as taking blood, routine vaccinations, administration of medications through intravenous, intramuscular, or subcutaneous routes, cannulation, or intra-oral injections. Several factors are thought to influence development of needle fear, including parental fear and previous painful or traumatic incidents (Taddio *et al.*, 2022; McMurtry *et al.*, 2015). A fear of needles could lead to avoidance behaviours, low adherence to treatment and a reluctance in seeking healthcare interventions (Sharif *et al.*, 2023; Sokolowski, Giovannitti and Boynes., 2010; Wright *et al.*, 2009; Kleinknecht and Lenz., 1989). Indeed, studies have shown that needle fear in adulthood is a barrier to engaging with healthcare, including acceptance of routine venepuncture (Alsbrooks and Hoerauf., 2022), vaccinations (Kowalsky., 2023; Taddio *et al.*, 2016), prenatal care (McAllister *et al.*, 2012) and dental care (Chidley and Burns-Nader 2024; Berge *et al.*, 2016; Wali *et al.*, 2016; Vika *et al.*, 2008) with a recent review confirming that there is no consensus on the most effective way to support children receiving intra-oral injections (Monteiro *et al.*, 2020).

In hospital settings, children have reported that the most fear-inducing procedures are those involving needles (Kortesluoma and Nikkonen., 2004). Needle fear can also influence the method of administration of medications (Duncanson *et al.*, 2021; Lee Mortensen and Rasmussen., 2017) and has been observed to prevent adults from being able to self-administer treatment at home (Costello, Kennedy, and Scanzillo., 2008; McLaughlin *et al.*, 2003). There is emerging evidence suggesting fear of needles may impact on childhood vaccination uptake (Taddio *et al.*, 2022) which could lead to the development of serious preventable diseases such as Human Papilloma Virus (HPV) (implicated in oral and cervical cancers) or measles. It could also lead to other negative health outcomes including poorer control of disease (Göthesson *et al.*, 2022), higher risk of complications, increased risk of mortality and poorer quality of life.

The health service may also be affected through higher numbers of missed appointments and the need for more invasive or intensive treatments due to delayed investigation or diagnosis of disease through delayed presentation or difficulty undertaking diagnostic tests.

Beyond the potential negative impacts to the children themselves, they can also be a source of occupational stress for healthcare providers administering needle-based procedures (NBPs) (Ives and Melrose., 2010; Moore and Brødsgaard., 2001; Dower *et al.*, 1995). Children who are not able to tolerate needles may move during procedures, which increases the risk of needle stick injury – another source of occupational stress (Wicker *et al.*, 2014). It has also been observed that some medical professionals may themselves have needle fear, which can cause them stress when undertaking these procedures on others (Jha *et al.*, 2023).

Childhood needle fear may also be a barrier to engagement and involvement with research. The Royal College of Paediatric and Child Health Ethics Advisory Committee has previously recognised that the process of enduring a NBP may be too distressing for some children to allow them to participate in certain studies (McIntosh *et al.*, 2000). It has also been noted that some parents may perceive that blood sampling causes pain and distress and are therefore reluctant to consent for the procedure (Chatio *et al.*, 2016). This seems to be supported by literature highlighting low participation rates in studies which require blood sampling (Kaguelidou *et al.*, 2013; Gattuso., 2006).

There is a paucity of evidence at the time of writing for the effective self-management of needle fear in childhood. Commonly known techniques have only been evaluated in an adult population thus far (McMurtry *et al.*, 2016; McMurtry *et al.*, 2015). Needle fear is likely to be multifaceted, with differing factors affecting the development and maintenance in childhood compared to adults. The assumption cannot be made that resources which are effective for an adult population will be effective in children. A Cochrane systematic review published in 2020 suggested that Cognitive Behavioural Therapy (CBT) is probably more effective than waiting lists or no treatment short term (James *et al.*, 2020). At present the quality and availability of evidence to confirm the effectiveness of CBT in young people is limited. CBT can be defined as a therapy which is based on the theory that a person's thoughts, feelings, behaviours, and symptoms are interlinked and all play a part in the maintenance of fear. The process of CBT involves identifying the causative thoughts and subsequent behaviours which are likely to be influencing the fear and then developing strategies to prevent these (Kennerly, Kirk and Westbrook., 2016).

This type of therapy has been shown to be effective in the reduction of fear related to injections when delivered by a trained professional such as a psychologist (Ost, Hellstron and Kaver., 1992).

Access to CBT can be facilitated through the National Health Service (NHS) Child and Adolescent Mental Health Service (CAMHS) but accessing these services can be complicated by long waiting lists and strained services. As part of the NHS recommended stepped care model, patients with lower levels of anxiety should be offered alternative treatment before considering referral to secondary care services such as CAMHS. These alternative treatments may provide a useful starting point for patients prior to onward referral and in some cases may provide successful treatment, removing the requirement for referral.

The NHS Long Term plan is currently under review. The plan looks ahead over the next 10 years and sets clear priorities for health services (NHS England, 2024). The previous plan aimed to widen the access for children and young people to services closer to home and reduce unnecessary delays in receiving care. The aim is to understand the needs of this cohort and provide care in ways which work for them. Previous studies have shown that CBT for adults with anxiety disorders including depression and obsessive-compulsive disorders is cost-effective over their lifetime (Hedman *et al.*, 2016). It can be considered that this may be even more beneficial if treatment can be provided in childhood. There is no specific evidence for the use of self-help CBT for the management or reduction in needle fear in a child population, but it is entirely reasonable based on the current evidence to hypothesise that the approach could be successful.

The development of a self-help resource will support children with needle fear to receive necessary healthcare interventions and may prevent these children carrying their fear into adulthood. It will have the potential to increase participation in research studies where blood samples or administration of medicines is required.

1.2 Aims and objectives

The overarching aim of this study is to develop and conduct a feasibility study of a self-help resource based on the principles of CBT to reduce needle fear in children and adolescents. The findings will inform the design of a future definitive study.

Aims:

1. To explore the views and experiences of children, young people and their families about the development and maintenance of needle fear

2. To explore the preferences of children, young people and their families for a self-help resource aimed at addressing their needle fear
3. To develop and conduct a feasibility study of a self-help resource to reduce needle fear in children and adolescents to inform a future definitive study

Objectives:

1. To undertake qualitative interviews with children, young people, and their families to gain a meaningful insight into their experiences of needle fear, and preferences for a self-help resource to address needle fear
2. To develop the self-help resource using a co-design approach with young people, parents and a variety of healthcare professionals based on the findings from the qualitative interviews
3. To conduct an uncontrolled feasibility study to address the following uncertainties:
 - a. The most appropriate self-report measure of needle fear (which will be the primary outcome for the future trial)
 - b. The perceptions of key stakeholders (such as phlebotomists, dentists, anaesthetists, school nurses) on the resource and on their willingness to recruit participants
 - c. Feasibility of recruitment
 - d. Retention and completion rates
 - e. Acceptability of the resource to children and their parents, and their willingness to be recruited
 - f. The practicality of administering the study protocol in three settings – paediatric medical, paediatric dental and schools

This thesis is laid out as follows:

Literature review

A review of the pertinent existing literature related to needle fear is presented in Chapter Two

Aims and objective of study

A summary of the aims and objectives of the study overall and related to each stage is presented in Chapter Three

Qualitative enquiry (Stage One)

A summary of the qualitative element of the study is presented in Chapter Four

Co-design of resource (Stage Two)

A summary of the co-design element of the study is presented in Chapter Five

Feasibility study (Stage Three)

A summary of the feasibility element of the study is presented in Chapter Six

Discussion

A discussion of the collated findings from the study is presented in Chapter Seven

Conclusions and recommendations

A summary of the final conclusions and recommendations which can be drawn from the findings of the study are presented in Chapter Eight

Chapter Two

2. Literature review

2.1 Introduction

2.1.1 Definition of needle fear

Fear and anxiety are often used interchangeably in the literature. It is posited that fear and anxiety are separate concepts, with general agreement that fear is felt in response to being presented with a specific stimulus, while anxiety does not have a specific stimulus (Ferusini and Panselo., 2015). For this review the term 'needle fear' is used to describe any avoidance, fear, anxiety, or distress caused by needles although it is acknowledged that there is a continuum from mild fear through to phobia. The phrases 'needle' and 'needle-based procedure' (NBP) relate to any healthcare procedure where a needle is used, such as taking blood, administering intravenous, intramuscular, or subcutaneous medications, routine inoculations, cannulation, or intra-oral injections.

2.1.2 Scope of the review

This literature review will aim to answer the following questions:

1. Why is there a need to reduce needle fear in children?
2. What measures and management strategies currently exist for children with fear of needles?
3. Which method of management is most appropriate for adaptation to a self-help resource?
4. How can children, families and healthcare workers best be engaged in the development of a self-help resource?

2.2 Exploration of children's needle fear

2.2.1 Prevalence of needle fear

According to the most recent systematic review and meta-analysis of needle fear, by McLenon and Rogers in 2019, the general worldwide prevalence of needle fear in adults aged 20-40 was between 20-30%, with a decrease noted as age increases (McLenon and Rogers., 2019). Of the 119 included studies, the larger population studies had been undertaken in the United States, Australia, India, Mexico, South Korea, the Netherlands, Sweden, and Germany. A scoping review of the prevalence and evidence-based management of needle fear in adults with chronic conditions in 2021 found that there is also a paucity of studies in this cohort. Of the studies which exist, it appears that this cohort may exhibit higher levels of needle fear: ranging from 17-52% in those with experience of chemotherapy, 25-47% in those with kidney failure and up to 80% of those with type 2 diabetes (Donaldson *et al.*, 2021). The most recent evaluation of a global adult cohort, by Alsbrooks and Hoerauf (2022) included 2098 participants and discovered a prevalence of 63.2% reporting fear of needles.

One of the difficulties in estimating general prevalence of needle fear, is the range of methods used for detection and measurement. Generic tools used to measure needle fear include the use of Visual Analog Scales (VAS), single item questions, interviewer administered structured questionnaires, and investigator created surveys (Duncanson *et al.*, 2021; McLenon and Rogers., 2019; Page *et al.*, 1997). A variety of specific clinical tools also exist, such as the Children's Fear Scale (CFS – McMurtry *et al.*, 2015), Dialysis Fear of Injection Questionnaire (DFIQ - Mulder *et al.*, 2013), Intra-oral Injection Fear Scale (IOIFs - Berge *et al.*, 2016) and Diabetes Fear of Injecting and Self-testing Questionnaire (D-FISQ) (Snoek *et al.*, 1997).

Measurement tools for needle fear will be explored in greater depth in Section 2.4.

The other acknowledged obstacle to more accurate measurements of needle fear in both children and adults, is that individuals with needle fear are less likely to present for procedures and therefore may be omitted from studies.

2.2.2 Prevalence of needle fear in childhood

According to the systematic review by McLenon and Rogers in 2019, needle fear affects around 50% of children and young people in the general population.

The authors included all publications where original research was presented on investigation of needle fear or phobia where data was included regarding the frequency of needle fear. Both articles focusing on general needle fear and specific blood-injection-injury phobia were included. Of 119 papers originally identified, only 35 met the inclusion criteria and contained enough information for meta-analysis. The included studies looked at an age range of three years – 75 years. Clinical studies with children typically included those with type 1 diabetes, and those in dental care settings. The authors determined that needle fear frequency was highest in children and decreased with age. They estimated that for every decade increase in age, the prevalence of needle fear decreased by 8.7%. The frequency of needle fear in adolescence ranged from 20 – 50%, while for 20-40 years old this had decreased to 20 – 30%.

The frequency of needle fear was observed to be higher in females, with a pooled needle fear prevalence ratio of 4:1 (female: male). For needle phobia, the pooled prevalence ratio was 7:1 female: male). A difference between countries was also observed, with higher levels of needle fear reported in Saudi Arabia and Israel, and lower levels in Sweden. Needle phobia was noted to be higher in Mexico and India, with South Korea and Germany reporting lower levels. Chronic health conditions, many of which require multiple NBPs, also seem to impact on children's levels of needle fear, with the literature suggesting that this ranges from up to 84% in children who have or are undergoing chemotherapy and up to 77.8% in children commencing immunotherapy treatment. Conversely children with type 1 diabetes appear to exhibit less fear of needles, with prevalence ranging from 1.4-34.2%.

The systematic review is limited by the availability of literature in the field, and by the characteristics of the original studies. It was noted that for population statistics not all samples were randomly selected. Clinical studies in some cases had small participant numbers, or selected patients through referrals only. There were several different measurement tools applied to measure needle fear or phobia, making direct comparison difficult. The authors concluded that a more unified approach to the assessment of prevalence of needle fear is required to accurately compare across different settings and countries.

2.2.3 Factors which support the development of needle fear

Fear is generally accepted as a human emotion which causes an individual to feel consciously afraid, and results in defensive responses. These defensive responses are also observed in the animal kingdom.

Some fears are described as being 'innate', meaning the individual will feel fear without having experienced any harm due to the threat previously, or having observed or learned the fear from others. Some examples of innate fears include heights, the dark, predators, aggression from others and pain (Silva, Gross, and Graff., 2016; Blanchard and Blanchard., 1989). Individuals can also 'learn' to be afraid of additional stimuli where a usually neutral stimulus acquires the ability to induce the same defensive responses. This can be referred to as a 'conditioned or learned' fear (Silva, Gross, and Graff., 2016).

There are three accepted pathways, first described by Rachman, by which an individual can acquire a fear: conditioning, vicarious exposure, and transmission of negative information (Rachman., 1991; Rachman., 1977).

Conditioning

Conditioning, or direct experience, is where a neutral stimulus becomes associated with a negative consequence such as pain. This causes the stimulus to become a fear trigger. The strength of the fear developed is thought to be determined by the number of negative experiences, and the intensity of the pain or fear experienced by the person at the time of exposure. A person can also then become frightened of similar objects or situations. The development of the fear encourages the person to engage in protective behaviours, such as avoidance (Rachman., 1991; Rachman., 1977).

Vicarious exposure

Vicarious exposure is described as an emotional response learned through vicarious experience (that is, an experience that happened to another). A neutral stimulus can become a fear trigger due to socially learning this through observing the experience of another (Rachman., 1991; Rachman., 1977). An original study is described by Rachman where it was observed that the fear (or lack thereof) of mothers related to air-raids during the war, was an important determinant of whether their children developed a similar fear.

Transmission of negative information

Rachman (1977) described that the giving of information is an integral part of raising a child. Children are given a steady stream of information from their parents and peers, especially in the earliest years.

It was suggested that this process of transmitting information is likely to provide the foundation for most encountered fears.

Summary

Rachman's theory of fear development acknowledged that three pathways are likely to be part of a complex interaction which is not well understood (Rachman 1977). His theory is widely accepted and referenced heavily within the published literature on development of fear. It was critically reviewed by King and colleagues in 1998, who determined that the current evidence base at the time generally supported the three pathways suggested by Rachman (1977). They also acknowledged that there was likely to be a more complex interaction at play, including genetic, environmental, and personal factors. They reported that there were clear reports in the literature of children who did not seem to fit into any of the three presently defined pathways. All the papers included in their review involved retrospective child or parental recall of causative factors related to the child's fear development which was referenced as a limitation due to possibility of recall bias. They concluded that further research into the aetiology of childhood fear and phobia is required, with future study designs to include prospective longitudinal studies of large cohorts (King *et al.*, 1998).

Development of needle fear

Nauman and colleagues discussed that the existing data supports the theory that the development of needle fear begins in childhood, a theory originally suggested by Ost in 1992 and more recently by the American Psychiatric Association (Nauman *et al.*, 2021; Ost, Fellenius, and Sterner., 1992). As discussed above, there are three main defined pathways by which fear can be acquired: conditioning, vicarious exposure, and transmission of negative information. These are discussed in relation to development of needle fear below. There are no prospective studies on pathways to needle fear development, possibly due to the ethical issues associated with purposefully inciting a child to develop fear. This research would be likely to be detrimental to the wellbeing of participants without providing any measurable clinical benefit and therefore would not be ethical to undertake.

Conditioning

Traumatic previous experiences have been shown to contribute to the development of acquired fears. In relation to needles, there are several studies which would support the hypothesis that a negative experience is a factor.

Kleinknecht and colleagues in 1994 conducted a study of a sample of 933 undergraduate students about their fears of blood, injection, and injury through self-report questionnaires. Of those with needle-related distress, 76% reported that the fear was related to a previous event. Ayers and colleagues explored needle fear of 16 children aged 7-17 years with cystic fibrosis through qualitative interviews, with some children reporting a previous negative exposure (Ayers *et al.*, 2011).

Children who experience a painful or traumatic experience with needles can then associate all future NBPs with this original negative experience. This causes mostly psychological symptoms such as extreme anxiety, panic attacks and pre-occupation with any upcoming procedures (Orenius *et al.*, 2018). Not all children who experience a traumatic NBP will go on to develop fear of needles, suggesting that direct experience alone would not explain the development of needle fear. Many adults with needle fear are not able to recall a specific incident which contributed to their anxiety around needles (Du *et al.*, 2008).

Vicarious exposure

Individuals who observe another being frightened can be conditioned to develop fear of the same stimulus without being exposed to it themselves. Kleinknecht reported that 20% of people in their 1994 study indicated a vicarious exposure as the cause of their needle fear. Immunisation Stress Related Responses (ISSRs) are reactions which occur due to the stress of being vaccinated, rather than a reaction to any of the contained products (World Health Organisation 2019). An example was described by Kharabsheh in 2001 of an incident which occurred in Jordan in 1998. Over 800 young people who had received a standard tetanus-diphtheria vaccination at school reported suffering side effects, with 122 being admitted to hospital. It was discovered that the majority of the children's 'symptoms' were psychological, rather than physical. Nauman described that there are over 200 published accounts of such mass responses to situations, including another example where more than 900 school students in China who had received the Japanese Encephalitis vaccine were admitted to hospital with side effects including nausea and fevers. There was no cause identified, suggesting this was likely related to observational learning (Nauman *et al.*, 2021). Children's fear of venepuncture is known to be related to the behaviour of the adult who accompanies them, with positive associations with distress-promoting behaviour such as criticism, lack of reassurance, apologising and poor empathy (Taylor, Sellick, and Greenwood., 2011; Mahoney, Ayers, and Seddon., 2010).

Transmission of negative information

Hearing and internalising negative information about needles may facilitate the development of needle fear (Nauman., 2021). Kleinknecht reported that only 3% of people in their 1994 study indicated information as the cause of their needle fear (Kleinknecht., 1994). Field and colleagues described in 2001 that negative information about a stimulus can explain the development or worsening of fear of stimulus which have not personally been experienced (Field, Argyris, and Knowles., 2001). This can cause the person to experience a fear response in relation to the stimulus, such as a needle, leaving them unable to participate or experience it and learn that there is no need to be frightened (Du *et al.*, 2008).

Noble and colleague's secondary analysis of qualitative data from patients with dental anxiety found children felt that knowledge shared by friends or family could have a direct impact on their needle fear (Noble *et al.*, 2020).

Additional factors

Fear of pain

Another factor which has been implicated in the development of needle fear is fear of pain. Some patients are more frightened of the possibility of the needle causing extreme pain, than they are of the needle itself (Ziegler *et al.*, 1999).

This finding was echoed by McMurtry and colleagues in their paper 'Far from a little poke' which aimed to provide a foundation for readers to understand the relationship between painful procedures and the subsequent development and maintenance of needle fear, strategies for preventing pain (and subsequent fear) and management of individuals who are already highly fearful. The authors reviewed published literature on the interventions for pain during NBPs and management of needle fear. They reported that greater perceived pain during an NBP is associated with higher levels of fear, and the emotional impact of needle pain lasted far beyond the initial exposure. They asserted that poor management of pain during NBPs was associated with the development of fearful memories which may be a predictor of future distress. Children and adults who have needle fear are also more likely to report pain from their procedures, and require more analgesia, with children exhibiting lower pain thresholds than adults. The authors suggested that if NBPs were painless, there could be an increase of 10% in willingness to be vaccinated over an individual's lifetime (McMurtry *et al.*, 2011).

Taddio's 2016 systematic review also suggested that pain could be a barrier to vaccine uptake in children, although the overall number and quality of the included studies was low (Taddio *et al.*, 2016).

Noel, McMurtry and colleagues (2018) described that children's memories can be susceptible to distortion – or incorrect recall – based on external or contextual factors, with memories of painful experiences being particularly susceptible. They undertook a systematic review and meta-analysis of memory-reframing interventions for children and adolescents undergoing needle procedures and presented their findings in a brief clinical report, in the hopes of encouraging future research. Only three studies could be found which met the inclusion criteria. The authors reported that the distorted pain memories of children and adolescents can cause them to remember them as more painful than they really were, causing them to experience more distress at future appointments. This highlighted the need for good pain management for patients undergoing NBPs, and further research into the strategies for management of those who have previous traumatic memories (Noel *et al.*, 2018).

Fear of fainting

Some individuals will suffer from vasovagal reactions related to needle fear. A vasovagal reaction results from an autonomic overreaction, where a sudden increase in heart rate and blood pressure is followed by an immediate reversal. This can result in reduced blood flow to the brain, and the person can feel dizzy and may faint. Orenius and colleagues suggested that individuals who faint during NBPs can report more fear of the syncope reaction than the actual procedure itself (Orenius *et al.*, 2018). This is based on a 2001 study, which included only 11 adults (Accurso *et al.*, 2001). No further research could be identified exploring the relationship between fear of fainting and fear of needles at the time of writing.

Fear of side effects

Some NBPs are associated with additional symptoms following their administration, particularly the injection of drugs. For example, local anaesthetic injections result in localised numbness, methotrexate injections are associated with nausea and headaches and propofol injection is associated with pain along vessels. These negative side effects can be significant in the development of the fear of these needles (Orenius *et al.*, 2018). Mulligan and colleagues reported in their 2013 paper that children undergoing methotrexate injection suffered more vomiting post treatment than children who were treated with methotrexate pills, thought to be associated with anticipatory nausea (Mulligan *et al.*, 2013).

Fear of losing control

Some children who have a fear of needles have associated combativeness. This stems from a combination of the fear of needles and a fear of being controlled, thought to originate most commonly from a previous episode of physical or emotional restraint during an NBP. When they are unable to escape or avoid the situation, these children can become aggressive and defiant (Orenius *et al.*, 2018). A qualitative analysis of needle fear in dentally anxious adolescents reported that children felt that being in control would reduce their fear of needles, while experiences where they had lost control were exacerbating to their needle fear (Noble *et al.*, 2020).

The literature is not exhaustive on the development of needle fear in childhood, with the above factors not guaranteeing that a person will develop needle fear. It is likely to be attributable to a combination of several factors and dependent on the susceptibility of the individual.

2.2.4 Factors which mitigate the development of needle fear

Just as there are factors which might support, or facilitate, the development of fear of needles, there are suggested factors which may help prevent the development of needle fear.

Prevention of pain

As described above, children have lower pain tolerance than adults, and are susceptible to experiencing higher discomfort during NBPs. They are also at risk of distorted recall, causing them to attribute higher levels of pain to the experience when remembering later. This in turn causes them greater distress in the future (Noel *et al.*, 2018). Children who are anxious about pain also tend to experience it more acutely, leading to a vicious cycle (McMurtry *et al.*, 2011). If children were to be provided with effective pain management during NBPs, it is therefore reasonable to assert that this may prevent the development of needle related fears, including fear of pain (McMurtry *et al.*, 2015).

Other factors

The literature on prevention of needle fear is scant, but it could be asserted that prevention of the causes of needle fear could prevent the development of needle fear. This would include the avoidance of traumatic experiences, preventing the child from observing an anxious person undergoing an NBP and preventing the child from being given negative information about needles and instead providing them with positive information.

Kleye and colleagues undertook a study, published in 2021, with the aim of exploring child-identified strategies to manage fear and pain during NBP in hospital settings in Sweden (Kleye *et al.*, 2021). Thirteen children aged four -12 from three healthcare units were included in the study and participated in semi-structured interviews. Three main themes emerged during the interviews: methods of self-support, methods of adult support, and environmental support. The children identified several ways that they could support themselves during their procedures, including being brave and speaking up for themselves rather than simply going along with what their parents or doctors thought was best, taking control of their thoughts, and controlling their body. Children discussed that they wanted to be able to choose how things would happen, and to be asked at each appointment in case they wanted to approach things differently each time. They appreciated being able to squeeze things (stress balls, chair arms, parent's hands) during appointments. The researchers also explored with the children how adults could help support and empower them during NBP.

Children identified that they wanted to be asked for their preference, rather than assuming an adult should choose for them, and to have the option to change their mind at any time. The children also suggested that they wanted information about their procedure and what would happen, but that it was important that this was given at the right time. Information given too early could increase their fear, and most children suggested the best time was immediately before their appointment or procedure so that they did not have a lot of time to think about it. Some children advised that they did not want any information about their procedure beforehand but would want to know afterwards what had been done. Adults could also support the children by allowing them to scream or make loud noises, instead of asking them to be quiet, as this allowed the children to experience less pain. Children also explained that adults often misinterpret screaming as a sign to stop, when they just wanted to use it as a coping mechanism. The final factor identified as a method for adults to support them was to allow children to bring a soft toy to their appointments rather than having to rely on their parent for comfort. In addition, children described how the environment could help to reduce their fear and pain.

Children were enthusiastic about opportunities to play and meet other children and be distracted. They suggested that child-friendly décor in the treatment room was helpful, as they would have things to look at and engage with to help distract themselves or give them things to talk about. Children also suggested having the option of a curtain or drape to prevent them from seeing the needle or any medicines which were being administered.

The Kleye study is one of the first to engage children in developing strategies which may help them with their fear of needles and supports the finding that children desire control over what happens to them and their bodies. This study was generally well designed and employed methods to support children in sharing their thoughts such as pictures and art equipment. Some limitations of the study are that adolescents were not included (children aged 12+) who may have provided additional or differing views and added to the breadth of information obtained. The interviews were undertaken within the hospital, which may have impacted on the experience and engagement of the children if they had anxieties around clinical settings or equipment. There was no description of alternative options being offered. The recruitment of patients purely from the hospital setting also limits the transferability of findings to children who have experience in different healthcare settings. Some of the strategies suggested by Kleye and colleagues could be helpful for some children with needle fear, but that this will ultimately be dependent on the nature of the NBP and the individual child. It is also unclear who completed the qualitative interviews with the children and parents, and whether this person was appropriately experienced in qualitative research (Kleye *et al.*, 2021).

There is a clear gap in the literature related to children's perceptions and needs in the management and prevention of needle fear.

2.2.5 Consequences of needle fear in childhood

Impact on health

Fear of needles is implicated in avoidance of necessary or recommended healthcare procedures. It is associated with avoidance of having venepuncture (necessary for diagnosis and monitoring of disease and medications), undergoing amniocentesis (a procedure for identifying foetal anomalies), having dental treatment, accepting pain relief, donating blood, and managing chronic disease (Chidley and Burns-Nader., 2024; Kowalsky., 2023; Sharif *et al.*, 2023; Alsbrooks and Hoerauf., 2022; Taddio *et al.*, 2022; McLenon and Rogers, 2019; Berge *et al.*, 2016; Taddio *et al.*, 2016; Wali *et al.*, 2016; McAllister *et al.*, 2012; Sokolowski, Giovannitti and Boynes., 2010; Wright *et al.*, 2009; Vika *et al.*, 2008; Kleinknecht and Lenz., 1989).

Sufferers of needle fear have a higher risk of morbidity and mortality due to their avoidance of healthcare interventions, even when they are aware that they are necessary. Fear of needles can have a major impact on a person's life, inhibiting their ability to travel, gain education, work in certain sectors (such as healthcare), or even cause legal difficulties where police mandated blood samples are refused. In extreme circumstances, needle fear has even been reported as causing death due to the associated vasovagal reaction, with Hamilton stating in his 1995 paper that 23 deaths could be attributed to this. However, he did not state the period over which these deaths occurred. (Hamilton., 1995).

The current literature suggests that needle fear has the potential to drastically affect a person's wellbeing and health outcomes in a variety of ways.

Impact on the management of chronic conditions

Although there is literature on the health impacts of needle fear in adult patients with chronic conditions, the literature is sparser regarding children. Despite this, several papers have reported that needle fear can negatively impact on the management of chronic conditions in childhood as discussed below.

Diabetes

Insulin dependent diabetics rely on artificial insulin administration to control their blood sugars. Aronson discussed the role of needle anxiety in the insulin adherence of adult insulin users, stating that up to 94% of insulin users have some symptoms of anxiety or distress related to needles. Children with newly diagnosed diabetes aged less than nine were reported to have the highest levels of needle fear, with a prevalence of 75% (Aronson., 2012). Several other studies assessing prevalence of needle fear in children with diabetes found that this ranged from 32-75%, with 22% reporting pain associated with self-injection (Taddio *et al.*, 2019). Karter and colleagues investigated barriers to initiation of insulin therapy. Amongst the patients who were not adherent to their insulin regimen, 13% reported that this was due to fear of self-injection. Patients also expressed concerns about pain related to injection. Patients have identified several factors which contribute to their fears around self-injecting, including poor counselling at diagnosis from healthcare providers, poor health literacy, lack of confidence and severity of disease (Karter *et al.*, 2010). Injection anxiety is associated with reduced self-testing, reduced number of insulin injections daily, poor control of blood sugar levels, increased risks of peripheral vascular issues and cardiac disease and poorer health outcomes (Aronson., 2012).

Oncology

Treatment for patients with cancer can often involve chemotherapy, usually delivered via intravenous infusion. Survival rates for childhood cancers in developed countries have improved greatly due to the introduction of chemotherapy protocols, from 40% in the 1970s to over 80% in 2020. It is acknowledged that while adult patients tend to suffer from more tumour-related pain, children tend to suffer pain because of their treatment and tests, rather than their cancer itself. These children are at higher risk of developing anxiety around treatment, including fear of needles, which places them at risk of non-compliance with care and significant morbidity or mortality as a result (Loeffen *et al.*, 2020). A clinical practice guideline was published by Loeffen and colleagues in 2020 to advise on pain and distress management techniques for these children during NBP, in the hopes of preventing this. The guideline was aimed at healthcare professionals who care for children with cancer, including oncologists, nurses, specialists, and anaesthesiologists. The recommendations are organised into three sections: minor procedures, lumbar punctures, and major procedures. Recommendations were made including placement of topical anaesthetic, use of oral analgesia, use of sedation or general anaesthetic, use of hypnosis, and use of distractions. The authors reminded clinicians that these options should also be considered alongside the type of procedure, the preferences of the patient and family, and the availability of these resources.

Learning difficulties and the autism spectrum

People who are autistic and those with learning difficulties are reported to suffer with higher levels of needle fear than the general population in the literature (Wolff and Symons, 2013; Edwards and Northway, 2011; Martin, Roy, and Wells, 1997) and by UK organisations including the Good School Guide and Thinking Autism (2021). It is also generally accepted that autism spectrum disorder is associated with anxiety (Vasa *et al.*, 2020; McVey, 2019; Spratt *et al.*, 2012) and sensory processing disturbances (Marco *et al.*, 2011; Leekham *et al.*, 2007). They may also respond differently to established distress reducing techniques.

Impact on vaccination

Needle fear has been implicated in vaccine refusal and reluctance in children. Studies have estimated that the prevalence of needle fear in children having vaccinations is up to 68% (Taddio *et al.*, 2019). A more recent systematic review by the same author estimates that the prevalence in the 'under vaccinated' paediatric population is 18%. In a sample of children in Canada, needle fear was associated with vaccine refusal in 8% of children and 7% of parents.

A study of Japanese children reported that 52.2% were unwilling to comply with vaccination, although this improved to 27.5% after an education event was delivered (McLenon and Rogers., 2018).

The Human Papilloma Virus (HPV) vaccine was designed to protect individuals from strains of HPV which contribute to the development of cervical cancer. It is delivered in two separate doses. A study by Baxter and colleagues published in 2017 suggested that needle fear could be a predictor for poorer uptake of the HPV vaccine, with the pre-adolescent individual's anxiety being a stronger predictor than any parental anxiety (Baxter *et al.*, 2017). Clark and colleagues asked the parents of children who were due to complete the second dose of the HPV vaccines to share their thoughts on whether they felt their children would complete the course and elaborate on any reason why their children may not comply (Clark *et al.*, 2016) . Only 54% of the parents were certain their children would accept the second dose, with 42.1% of these stating that their child's fear of needles would be the reason they may not continue with the programme. This supports the theory that fear of needles is a contributory factor in vaccine non-compliance.

In summary, children can suffer from impacts related to needle fear including difficulty administering or accepting treatment for acute and chronic health conditions, difficulty accepting vaccination for serious but preventable diseases, difficulty accepting lifesaving treatment and are at risk for poorer quality of life and a more restricted lifestyle than their peers. There is also a paucity of research investigating the impact of needle fear in children on their parents, caregivers, or other family members.

Impact on healthcare professionals and health services

Patients who are anxious of needles and injections can themselves be a source of stress to healthcare providers. Dower and colleagues described a survey of 711 California based dentists, asking them "Is there one type of patient that seems to make you the most anxious about giving injections? If so, please describe this type of patient". Two thirds of the respondents described anxious patients, and 16% identified children (Dower *et al.*, 1995).

Nurses are another group of healthcare provider who are known to suffer stress related to patients with needle fear. Ives and Melrose (2010) explored the feelings and experiences of nurses in the management of needle phobic patients, with nurses reporting that they 'dreaded' immunising needle resistant children, especially in the early stages of their careers. They described such encounters as 'awkward, difficult and complex'.

Nurses also reported feeling worried about making a mistake or hurting the patient, as well as worries for their own safety. They had ethical concerns about continuing to immunise children who were very distressed or being held by parents, seeing it as akin to assault. Nurses generally reported feeling emotionally exhausted, tired, unsupported, and drained by their experiences, and felt hurt when parents cast them as the 'villain' of the experience.

There is a paucity of research investigating or reporting the impact of needle fear in children on the wider health service, such as through missed appointments, requirements for number of appointments or use of resources.

2.2.6 Summary

Needle fear is common in children and adolescents and has the potential for a variety of negative impacts on their health. The development and maintenance of needle fear in children has not been exhaustively studied but several important factors have emerged which relate to the environment in which the child is exposed to a needle, or to information about needles, during their earliest experiences. There are likely further interlinking or contextual factors, and individual factors which increase susceptibility to development of needle fear. Due to the complex nature of fear development, and the lack of true understanding about individual susceptibility, there are no clear preventative strategies other than to avoid negative information and experiences – which may not be sufficient for all. In this case, and while research into childhood needle fear continues to progress, it is essential that children with fear of needles are managed appropriately with the aim of addressing or lessening their anxiety to allow them to accept necessary procedures. The strategies and treatments which currently exist for children are discussed in Section 2.3 below.

2.3 Management of needle fear

Several management strategies have been proposed to assist people in reducing, or coping with, their fear of needles. Some strategies are designed to be self-guided while others are supported or delivered by health care professionals. These management strategies include the applied tension technique; relaxation techniques; sedation; prevention of pain; graded exposure; cognitive behavioural therapy; preparation; and support and distraction. These techniques are explored in more detail in Sections 2.3.1 and 2.3.2 below.

There are currently no official guidelines available for the management of needle fear in the United Kingdom, although individual studies and reviews recommend treatment based on best available evidence.

Techniques can be categorised based on whether they are designed to address the physiological symptoms, or the unhelpful thoughts and feelings associated with the fear of needles. Two systematic reviews have been published within the last ten years, assessing the evidence for treatment of needle fear by McMurtry and colleagues in 2015 and Birnie and colleagues Cochrane review in 2018.

McMurtry and colleagues undertook a systematic review of management techniques for individuals with high levels of needle fear. They aimed to synthesise the evidence for specific exposure-based interventions for the management of needle fear in both children and adults (McMurtry *et al.*, 2015). They assessed the quality of evidence for in vivo exposure (graded exposure), multiple vs single sessions of in vivo exposure and non in vivo exposure such as the use of computer or imagined stimulus. Additionally, they assessed the applied tension technique vs exposure alone for reduction of fainting. They included all papers where the participants had high levels of needle fear (including blood-injection-injury phobia) and were having an NBP, where the study was a randomised or quasi-randomised design and included at least 5 participants undergoing an exposure-based intervention and where an outcome of interest was reported. All published papers including academic theses were eligible for inclusion. Some additional papers which included participants with a differing specific phobia were included if they underwent an exposure-based treatment and the paper reported an outcome of interest.

The outcomes of interest were measurement of specific fear, general fear, compliance, pain, distress, procedure outcomes, memory, and preferences. In total 11 papers were included in the review, with six studies focusing on children and five focusing on adults only. The main reasons for excluding other papers were study design (case reports or non-randomised) or incorrect population (not needle fear). None of the trials included for children specifically examined the effectiveness of in vivo exposure for children with needle fear (although they were present in the sample) or reported results separately for the children with needle fear. The findings of this systematic review related to each management type are discussed in the relevant sections below. Overall, the authors concluded that there is a paucity of high-quality research in the management of needle fear in children and adults. When reviewing the broader literature on phobias, there is evidence that both in vivo and non in vivo therapy can be effective in the reduction of needle fear, with multiple sessions not clearly superior to a single session.

Birnie and colleagues undertook a Cochrane systematic review of psychological interventions for needle-related procedural pain and distress in children and adults.

They aimed to assess the efficacy of psychological interventions for needle related procedural pain and distress in both children and adolescents (Birnie *et al.*, 2018). This was an update of a Cochrane review which has had four iterations to date (2005, 2006, 2013 and 2018). They included all peer reviewed published randomised controlled trials (RCTs) which included at least five participants in each arm of the study and compared a psychological intervention for needle fear with a control or comparison group. Participants were aged 2-19 years old, and all NBPs were included. Two review authors assessed risks of bias and extracted data. In total, 59 trials were included, with 5550 participants. The findings of this systematic review related to each management type are discussed in the relevant sections below.

Overall, the authors concluded that the evidence supported the efficacy of hypnosis, distraction techniques, breathing intervention and combined cognitive behavioural therapy for reducing needle fear and pain in children. The quality of trials and the overall evidence base was classed as low to very low. There is an identified need for more rigorous methodology in future trials, and better reporting of findings. The authors summarised by stating that despite the low-quality evidence, the potential benefits in reducing distress and/or pain for children supports the use of these techniques in clinical practice. The review was revisited in 2020, with the authors determining that there were no new relevant papers likely to change the conclusions. It is expected that this review will be updated as and when relevant new evidence is published. To date, no such update has been commissioned.

The sections below detail the methods currently available for management of needle fear in children and review the evidence available for each. Unless specified, none of the studies detailed below specifically screened children for the presence or level of needle fear.

2.3.1 Techniques to address physical symptoms

Applied tension technique

Fear of fainting is thought to be a factor in the development of needle fear, as described in Section 2.2.3. Some patients will suffer from vasovagal reactions when exposed to needle-based situations which can cause them to faint. The applied tension technique (ATT) is designed to interrupt this process and stop the person from developing and succumbing to these physical symptoms. The suggested steps involve tensing muscle groups for periods of 10-15 seconds before releasing and repeating every 20-30 seconds (appendix 1).

This technique can be completed by an individual completing the steps alone, or through training by a professional. The ATT has been shown to be beneficial in the prevention of fainting in individuals with a blood-injection-injury phobia (BII), which is characterised by a syncope-like reaction when exposed to blood, wounds, or needles (McMurtry *et al.*, 2015; Holly, Balegh, and Ditto., 2011; Ost, Fellenius, and Sterner., 1991; Öst, Sterner, and Fellenius., 1989).

McMurtry and colleagues undertook their systematic review of management techniques for individuals with high levels of needle fear in 2015. They identified all randomised or quasi-randomised trials of high quality which investigated management of high needle fear or phobia in children and adults as part of their analysis. Only one study on ATT was suitable for inclusion in their analysis, a 1991 study by Öst, Fellenius, and Sterner which is described in detail below. No studies could be found examining the use of the technique with child participants. The authors concluded from this one study that the ATT technique is an effective management to reduce fainting in adults, with evidence of long-term maintenance of effect at 1 year (McMurtry *et al.*, 2015).

One of the earliest investigations of the ATT was by Öst, Sterner and Fellenius in 1989, assessing its impact versus an applied relaxation technique (ART), with a subsequent similar study in 1991 aiming to determine which aspects of ATT were most beneficial to patients. Only patients with a diagnosed blood-injection-injury (BII) phobia were eligible for inclusion in each study, patients with isolated needle phobia were excluded. In the first study, 30 adult patients (19 women and 11 men) aged 18-51 years were recruited from a psychiatric hospital in Sweden. Patients were randomised to receive either five sessions of ATT, nine sessions of ART or ten sessions of combined therapy. It was reported that 22 of the patients had a positive fainting history (Öst, Sterner and Fellenius., 1989).

In the second study 31 adult patients (21 women and 9 men) aged 18-55 years old were recruited from the same hospital. Patients were randomised to receive five sessions of either ATT, exposure in vivo (EIV) or tension-only (TO) (Öst, Sterner and Fellenius., 1991). In both studies, before their treatment began, participants were asked to watch a 30-minute video containing the phobic stimuli and advised that it could be stopped at any time. Participants were assessed using proxy observation of behaviour (closing eyes, fainting, or ending the video); physiological measures (blood pressure and heart rate); and self-report measures (both studies included the Mutilation Questionnaire – Klorman *et al.*, 1974; and Fear Survey Schedule III – Wolpe and Lang., 1964, the 1991 study additionally included the Fear Questionnaire – Marks and Mathews 1979).

The participants in study one (1989) were followed up at six months, while the participants in study two (1991) were followed up at one year. In study one, a total of 11 participants fainted or almost fainted during the pre-treatment viewing. The authors stated that all three treatment methods were successful, with participants showing improved scores in all measures except diastolic blood pressure. A total of five patients were reported to have fainted at post-treatment follow-up. The authors concluded that further research in the management of blood phobias should focus on ATT, and that it would be beneficial to investigate if the treatment time could be reduced. In study two, a total of 14 participants fainted or nearly fainted during the pre-treatment viewing. The authors state that all three treatment methods were successful, with participants showing improved scores in all measures, although blood pressure scores were excluded due to repeated equipment malfunctions. When assessing for maintenance of the effect at one year follow-up, the authors reported that 100% of the ATT group, 90% of the TO group and only 40% of the EIV group had maintained improvement. The authors concluded that the ATT and TO methods should be investigated further, with focus on reducing treatment time to assess if this is still effective.

The limitation of both studies is that they did not include any patients with needle fear, rather than BII phobia, which is a recognised separate condition, and therefore it cannot be concluded whether the techniques might benefit this population.

More recently, two linked studies have evaluated the impact of ATT on the anxiety and fainting behaviours of adult blood donors (Holly, Balegh and Ditto 2020). The first study recruited 67 students (35 women and 32 men) aged 18-30 from McGill University in Montreal. Participants were required to have less than five experiences of blood donation. The students were randomised to have training in ATT or no training, followed by watching a moderately intense video featuring scenes of blood drawing procedures. Prior to commencing, participants completed self-report measures (medical fears survey and state-trait anxiety inventory) and had their blood pressure and heart rate monitored. Following completion of the video, participants completed the state-trait anxiety inventory and the blood donation reaction inventory. The results indicated a significant decrease in systolic blood pressure in the ATT group during the video amongst those who reported previous vasovagal symptoms. The authors determined that focusing on a specific population of blood donors in their second study would be more beneficial than a general young adult population.

They recruited 1254 blood donors (653 women and 601 men) from a mobile blood donation clinic in Montreal, which attended local colleges and universities. Participants ranged from 18-40 years and, as with the previous study, were required to have less than five previous experiences of blood donation.

Participants were randomised to one of three groups. Group one watched an instructional video on ATT and were then asked to practise it constantly while they were in the donation chair. Group two learned ATT but were asked to practise it only before the needle was inserted. Group three did not learn ATT and underwent standard blood donation procedure. The participants were asked to complete the blood donation reaction inventory and the medical fear survey after their procedure. As the population of Quebec speak French as their primary language the medical fear survey could only be administered to participants who understood English (half) as it was not validated in French. The results indicated that there was a strong reduction in needle fear in the participants ($F=32.46$) despite the assumption that needle fear would be limited in this population. People with higher levels of needle fear reported more symptoms such as dizziness and light-headedness. Women with needle fear who practised ATT reported significantly less symptoms during the blood donation procedure than women who did not practise ATT. The benefits were limited mostly to those with higher levels of fear. The authors concluded that ATT may be useful in several health-related contexts. The limitation of this study was the population of participants, all of whom had experience of blood donation, meaning it cannot be generalised to a wider population.

The limitations of the above studies were all related to their population of participants. Patients from the general population with needle fear have not been included in any high-quality studies to date reviewing the effectiveness of the ATT technique. There is limited literature evaluating the technique in adult patients and no literature on the effectiveness of the technique in a paediatric population.

The ATT technique appears to have promise as an effective management technique for individuals with syncope-like reactions when exposed to needles, such as experienced by persons with BII. It is recommended through information leaflets and advice from charities, pharmacies, and specific NHS Trusts. It does not address unhelpful thoughts or feelings related to fear, purely the physiological symptoms, and there is no evidence that the technique is effective for individuals with needle fear alone, or for children and young people.

Relaxation techniques

Relaxation is often recommended for individuals with needle fear, to help address the associated physiological symptoms. There are various relaxation techniques available, many of which rely on breathing or muscle control. The techniques can be completed by an individual without the need for specific training or equipment (appendix 2).

Relaxation techniques have not been thoroughly investigated as a method for reducing needle fear in the published literature (McMurtry *et al.*, 2015; Nilsson *et al.*, 2015; Heaton *et al.*, 2013).

McMurtry and colleagues' systematic review into management techniques for high needle fear identified only one study on relaxation which was suitable for inclusion in their analysis, a 2013 study by Heaton and colleagues which is described in detail below. No studies could be found examining the use of the technique with child participants. The authors concluded that non in vivo relaxation techniques are effective in reducing needle fear in adults (McMurtry *et al.*, 2015).

Further to earlier research describing the development and early use, Heaton and colleagues undertook a study assessing the effectiveness of a Computer Assisted Relaxation Learning (CARL) which is designed to reduce fear of dental injections (Heaton *et al.*, 2013). The study was undertaken in eight dental practices in Washington in the United States. In total, 84 adult participants (55 female and 29 male) were randomised to receive treatment with CARL or an information leaflet for standard care. Of these, 68 participants completed the trial, with 34 in each arm. Participants did not receive an injection during the trial. Participants were asked to complete four self-report measures before and after their sessions: The Modified Interval Scale of Anxiety Response (Modified ISAR), the Modified Dental Anxiety Scale (MDAS), the Dental Fear Survey (DFS) and the Needle Survey (NS). Mean fear scores were reduced in both groups, with a higher decrease in the CARL group. The differences between the MDAS groups were statistically significant (12.5 vs. 18.5, effect size 1.42, $p < .001$). Subsequently, 12 of the CARL participants opted to return for injection compared to six of the control participants. All received their injection successfully. The small sample of participants who returned for treatment meant that statistical testing had low power and no conclusions could be drawn. The authors concluded that CARL was successful in reducing dental injection fear compared to a standard information leaflet. The limitation of this study was that the programme was only tested on participants with dental fear or fear of dental injections, and it is unclear whether the fears were connected or whether the technique would be effective during other procedures or in other populations.

Another relaxation technique is guided relaxation, which has been assessed for impact on the stress and pain levels of 11–12-year-old girls undergoing their HPV vaccinations. The authors undertook a randomised crossover trial in three areas in Western Sweden (Nilsson *et al.*, 2015). At the time of undertaking the work only females routinely received this vaccination. A total of 37 girls were recruited and randomised to receive either standard care or guided imagery and relaxation for their first vaccination. The determination of appropriate sample size was not discussed.

The girls then received the opposite intervention for their second vaccination. Salivary cortisol levels were collected before the procedure and again 30 minutes after it was completed. The children were also asked to record their stress levels after the procedure on the Verbal Rating Scale Stress (VRSS) which is scored from 0 – least stress to 5 – most stressed. The results indicated that the salivary cortisol decreased in both groups during their second vaccination. This reduction was found to be statistically significant, although the children did not self-report a corresponding reduction in stress. The authors concluded that there is currently insufficient evidence to support the benefit of relaxation and guided imagery in this cohort. They suggest further research should focus on the use of this technique in more unpleasant procedures. The limitations of this study were that it was tested in a small sample, with no sample size justification, which excluded males (although this was reasonable at the time) and it cannot be generalised to the wider population and the lack of screening during recruitment, meaning it was not specifically tested in a population with known fear of needles.

Relaxation techniques have also been recommended for use alongside other methods, such as needle desensitisation. Taylor and Campbell strongly recommended that it be used in the management of intra-oral injection fear in paediatric patients. The authors suggested that in their expert opinion this is imperative to the success of their desensitisation protocol (Taylor and Campbell., 2015).

The limitations of the above studies were mainly their participant population. Patients from the general population with needle fear have not been included in any high-quality studies to date reviewing the effectiveness of relaxation techniques. The paediatric study did not share their sample size calculation, making it unclear if this sample size was sufficient to draw conclusions. There is also no evidence of the effectiveness of the technique in a paediatric population.

Relaxation techniques appear to have potential as an effective management of physiological symptoms for adult individuals with fear of dental injections. It does not address unhelpful thoughts or feelings related to fear, purely the physiological symptoms, and there is no evidence that the technique is effective for children and young people.

Sedation

Conscious sedation is a controlled, medication induced, depressed level of consciousness.

Two studies identified in the literature assessed the impact of sedation in the management of anxiety during NBPs in children undergoing oncology procedures (Dufresne *et al.*, 2010; Hedén, von Essen, and Ljungman., 2009).

Hedén and colleagues sought to determine the effectiveness of oral midazolam versus a placebo treatment in the reduction of pain, distress, and fear during paediatric subcutaneous port placement (Hedén, von Essen, and Ljungman., 2009). The study was set in a paediatric oncology/haematology unit in Sweden. In total 50 children (26 girls and 24 boys) were recruited and randomised to receive either oral midazolam or placebo medication. The authors determined that to achieve a power of 0.8 and alpha rate of 0.05 they would require 25 children in each arm. Participants and practitioners were blinded – the placebo drink was matched for the bitter flavour of the midazolam. Parents were asked to complete a Visual Analog Scale (VAS) for their child within 15-30 minutes after the procedure. Children over the age of seven years (25 participants) were asked to self-complete a VAS around one hour after their procedure, when they would no longer be sedated. The scale ranged from 0-100mm. It is not reported which precise question was posed to the participants when asking them to complete their scores. The child reported VAS means were 3.6 in the midazolam group and 22.9 in the placebo group. The parent reported VAS means were 12.3 in the midazolam group and 41.2 in the placebo group. The nurse reported VAS means were 14.4 in the midazolam group and 40.7 in the placebo group. The authors accepted a minimally important difference of 15mm, in keeping with that suggested for VAS pain scales. Using this measure, they asserted that there is a meaningful difference between the scores in each group, and therefore an argument for the use of oral midazolam in this cohort. The limitations of this study were the singular record of levels of fear meaning an assessment for reduction in needle fear cannot be made, the delay in asking parents to report scores post procedure, and the specificity of the sample population meaning the results cannot be generalised to the wider population.

A Canadian study focused on the standard use of intravenous sedation with local analgesia for oncology related NBPs in the department of paediatrics (Dufresne *et al.*, 2010). The authors aimed to assess the levels of fear and pain experienced during these procedures (Dufresne *et al.*, 2010). The sample included 14 children aged six to 12 years (six girls and eight boys). There is also no description of how the authors determined an appropriate sample size. The children were asked to complete a VAS to indicate their anxiety at four different time-points: prior to entry to the procedure room; prior to administration of the sedative agent; upon immediate completion of the first NBP; prior to departure from the procedure room. The VAS scores were recorded in cm rather than mm. It is not reported which precise question was posed to the participants when asking them to complete their scores.

Children over ten were also asked to record a score on the State Trait Anxiety Inventory at time-point one. The authors report that the children had a mean anxiety VAS score of 2.73 prior to entry and 2.93 just prior to sedation. The scores for the remaining time-points were not reported in the article. The authors also stated that the VAS was well correlated with the 'other scales' but do not quantify this. The authors concluded that sedation is beneficial to these children in terms of reducing reported pain and anxiety scores. The limitations of this study were mainly around poor reporting. The calculation for sample size, results for time-points other than the pre-procedural score and the correlation for other scales are not reported within the paper, ensuring that meaningful conclusions cannot be drawn. The authors have failed to evidence their conclusions within this paper. The additional limitation was the specific cohort of participants, meaning the results could not be more widely generalised.

Prevention of pain

Topical anaesthetics are medicaments applied to the skin to mitigate pain associated with a needle insertion, such as EMLA® cream. The effectiveness of topical anaesthetic in the reduction of pain and fear has been assessed in some studies in paediatric populations (Suleman *et al.*, 2024; May *et al.*, 2023; Stoltz and Manworren., 2017; Hedén, von Essen, and Ljungman., 2016; Brenner *et al.*, 2013). Pain relief through the use of analgesics, systemic medication, has also been considered as beneficial for children undergoing NBPs as an attempt to reduce their pain, and therefore associated distress (Çelik and Düzakaya., 2024; Hedén, von Essen, and Ljungman., 2014; Hedén, von Essen, and Ljungman., 2011).

Topical Anaesthetic

One topical anaesthetic which can be used to manage procedural pain is lidocaine. Brenner and colleagues published their work, undertaken in one site of a multisite academic emergency department in America, assessing the impact of a 15-minute application of 4% lidocaine topical anaesthetic versus placebo on pain and fear in children aged five to 18 years requiring urgent venepuncture or cannulation (Brenner *et al.*, 2013). Overall, 114 children (70 girls and 44 boys) were recruited and randomised to receive either topical lidocaine or a placebo cream. The study was designed to be double blinded, with participants and researchers were blinded to the intervention, although it is acknowledged that lidocaine can elicit side effects such as redness, discomfort, itching or localised rash that may not be evident in the placebo. There is no description of how the authors determined an appropriate sample size. The children were asked to complete a Visual Analog Scale indicating their anxiety within 15 minutes of cream application, immediately after the procedure, and within

30 minutes of the procedure being completed. It is not reported which precise question was posed to the participants when asking them to complete their scores (range 0-100). The heart rate of the children was also monitored at the same timepoints. The VAS scores reduced in all children post treatment, with the lowest pre-treatment score in the lidocaine group. On average, the children's heart rate increased by 8.8bpm between having the cream applied and immediately after the procedure and decreased by 11.4 bpm between the procedure and post-procedure. The exact scores for each group for timings two and three is not reported within the paper. The authors concluded that there is no evidence that a 15-minute application of lidocaine cream prior to treatment decreases pain or anxiety in this cohort. The limitations specific to this study were the failure to justify the sample size, meaning it cannot be ascertained if this study was adequately powered.

Swedish researchers completed a similar study, this time considering the impact of a topical anaesthetic for use during subcutaneous port insertion in the paediatric haematology/oncology unit of a Swedish hospital (Hedén, von Essen, and Ljungman., 2016). A sample of 151 children aged one to 18 years old were recruited. There is no description of how the authors determined an appropriate sample size. All children received a topical anaesthetic mixture 60 minutes prior to their planned procedure. One of their parents was asked to complete a Visual Analog Score on behalf of their child between five to 15 minutes after the procedure was completed. The parent was asked "how much fear did your child experience when the needle was inserted?" and "how much fear did you experience when the needle was inserted?". Cortisol serum levels were also taken from the child at the time of the needle insertion, and 30 minutes later. The mean VAS was reported as 28 during needle insertion, with a parental mean fear of 9. The mean cortisol levels were 205mmol/L at the time of needle insertion and 177mmol/L 30 minutes later – a change of 28mmol/L.

Cortisol does not increase for a period of around 30 minutes after fear is felt – the authors acknowledge that the first sample therefore is not a baseline score, but more likely to represent the fear felt near the beginning of the procedure. Fear perceived by the parent was shown to correlate with perception of pain, but this was not statistically significant. The authors suggested that this study shows that fear plays a role in pain perception in this cohort. The limitations of this study were its specific participant population, meaning the results cannot be generalised to a wider population, the failure to justify sample size and the lack of screening during recruitment, meaning it was not specifically tested in a population with known fear of needles. There was no pre-procedural VAS score taken so additionally no conclusions could be drawn regarding the effectiveness of the intervention on fear or pain experienced even in this specific cohort. The VAS score was also recorded by a proxy (the parent) meaning it may not accurately represent the child's experience.

The use of cortisol for measuring the child's anxiety was not unreasonable but given that the authors were aware of delay in cortisol changing this has not been accounted for in the timing of its measurement.

Stoltz and Manworren investigated the effects of a topical anaesthetic cream (EMLA®) on pain and anxiety compared with a novel 'needle-less' injection system (J-Tip®) in the peri-anaesthetic care unit of a medical centre in North-eastern America. Their population was children undergoing intravenous access prior to a procedure under general anaesthetic (Stoltz and Manworren, 2017). A sample size was estimated from previous research in the field, aiming for a power of 0.8 and an acceptable type 1a error size of 0.05, giving a target of 130 participants. The target effect size is described as 'medium' but not quantified. It was assumed that dropout would be up to 15%, so an overall target of 150 participants was sought. A convenience sample of 150 consecutive patients (72 girls and 78 boys) aged eight to 18-years who attended for a planned IV access in the unit was taken, and children were randomised to receive either the EMLA® or J-Tip® intervention. The study could not be blinded due to the obvious nature of the intervention. Children were asked to self-report their anxiety on the CFS at three specific time-points: completion of consent for procedure, five minutes prior to their IV insertion and immediately after IV insertion. It is not reported which precise question was posed to the participants when asking them to complete their scores. There was no statistically significant difference between the two groups, but it was observed that the anxiety decreased over time ($p=0.83$ between time one and two, $p=0.023$ between time two and three and $p=0.009$ between time 1 and 3). The EMLA® cohort reported a mean pre-operative score of 1.11 and a post-operative score of 0.79, with the J-Tip® group reporting a mean pre-operative score of 1.25 and a mean post-operative score of 1.07 ($p=0.314$). The authors concluded that there was no significant difference in the effectiveness of topical anaesthetic or injection system in terms of anxiety management, but both seemed to reduce anxiety and pain. The limitations specific to this study were that there was no control group, meaning it cannot be assessed whether needle fear would have decreased in this population even in the absence of the intervention.

A systematic review of the literature comparing the use of liposomal lidocaine and tetracaine hydrochloride topical anaesthetic creams in the management of needle-related pain was then published in 2023 (May *et al.*, 2023). The authors completed a literature search, including only studies which assessed the target topical creams, were randomised controlled or controlled clinical trials, included participants aged six+ years old undergoing either venepuncture, cannulation, intramuscular injection or subcutaneous drainage procedures. Only one study was discovered which met the inclusion criteria, a paper by Poonai and colleagues in 2012.

This study included 58 children from a hospital in Canada who were randomised to application for either Ametop or Maxilene topical anaesthetic prior to either venepuncture or cannulation. The primary outcome measure was change in mean pain scores using a self-reported scale – the Faces Pain Scale (FPS-R). The authors found no statistically significant difference in pain scores between the groups, concluding there was no clear difference between the topical anaesthetics (Poonai *et al.*, 2012). May and colleagues concluded that further research would be needed to assess the effectiveness of one cream over the other, due to the paucity of high-quality studies available for inclusion in the review.

The most recent study investigating topical anaesthetics in the management of paediatric needle fear was published by Suleman and colleagues in 2024. They aimed to assess the effectiveness of a topical anaesthetic cream called TKTIX with a distraction colouring book called TICK-B, compared to children receiving either TKTIX alone, the TICK-B alone or no intervention. The target population was children aged six to 12 years old requiring venepuncture. Overall, 176 children (87 girls and 89 boys) were recruited and randomised from a teaching Hospital in Iraq. Children completed the Wong-Baker FACES scale to measure pain during and after the procedure, although all the other measures were completed by a parent or nurse. The reason for this is not explained within the paper. Children's fear levels were assessed through parental assessment of their expression during treatment using the Children's Fear Scale (CFS). It is worth noting that the CFS is used inappropriately in this study, as it is a scale which was designed for children to self-report their fear, not as a proxy tool for use by others.

After treatment, parents and an observing nurse were asked to complete a Visual Analog Scale to record their assessment of the child's fear and pain. The question accompanying the proxy reports was not described in the paper. The fear score differences are not described clearly in the paper as it appears that the authors are reporting on two different timepoints which they have failed to clarify. They first state that the fear results were only statistically significant between the TICK-B and control groups, with the TICK-B only group having mean scores of 1.82 while the control group mean was 3.27. They then state that the fear results were only statistically significant between the combined treatment and control groups, with the combined group having mean scores of 0.93 while the control group was 2.83. The authors concluded that the combined treatment is most effective in controlling pain, and in managing fear pre and post procedure, while the TICK-B only intervention is most effective at the management of fear during the procedure. The limitations specific to this study were the use of proxy reports for child fear, which are known to be less accurate than self-report measures and the incorrect use of the CFS for enabling parents to proxy report anxiety.

Some common limitations across studies were their participant populations, which are insufficient to generalise to a wider population, and the lack of screening during recruitment, meaning none of these interventions were specifically tested in populations with a known fear of needles.

Topical anaesthetic appears to have potential as an effective management of pain/fear related to pain for children and young people with fear of needles. It does not address physiological symptoms, unhelpful thoughts or feelings related to fear.

Analgesia

Various types of analgesia can be provided to aid young people during NBPs. One powerful analgesic which may be considered is oral morphine. Swedish researchers Hedén, von Essen, and Ljungman continued their work with paediatric oncology patients in their 2011 paper, investigating the impact of oral morphine combined with topical anaesthesia for the management of fear and pain in paediatric oncology patients in a hospital in Sweden (Hedén, von Essen, and Ljungman., 2011). They aimed to assess the technique during the insertion of intravenous ports in children aged one to 18 years. A total of 50 children (22 girls and 28 boys) were recruited and randomised to receive oral morphine or a placebo. There is no description of how the authors determined an appropriate sample size. The study was triple blinded until data analysis had been completed. All parents, nurses and 27 of the children who were over the age of seven were asked to complete the VAS 15-30 minutes after the needle procedure. They were asked “How much fear did you/your child/the child experience when the needle was inserted?” with the scale ranging from no fear (0) to worst possible fear (100), and “How much distress did you/your child/the child experience when the needle was inserted?” with the scale ranging from no distress to the worst possible distress . The mean VAS for the children who received the morphine was self-reported as 8.1, parent reported as 23 and nurse reported as 26. The mean VAS for the children who received the placebo was self-reported as 10.5, parent reported as 21 and nurse reported as 17.6. Accepting the minimally important difference as 15 mm, as described in previous studies on the use of the VAS to measure pain outcomes, the authors concluded that there is no evidence for the use of oral morphine for reducing anxiety in this cohort.

The same team then undertook further research with children in paediatric oncology settings, investigating the potential impact of oral paracetamol on the fear and pain suffered by patients during placement of subcutaneous intravenous ports. The study was undertaken in the paediatric haematology/oncology unit of a Swedish hospital (Hedén, von Essen, and Ljungman., 2014).

They recruited 51 children (23 girls and 28 boys) aged one to 18 years who were then randomised to receive either oral paracetamol or placebo alongside topical anaesthetic application. The authors determined that a sample size of at least 50 was required to achieve a power of 0.8 and an alpha value of 0.05. Children were given either the paracetamol or placebo crushed into yoghurt or jam 60 minutes prior to their procedure. Parents and nurses were asked to complete a VAS on the child's anxiety five to 15 minutes after their procedure. Children aged over seven years (25 participants) were asked to complete a VAS immediately after their procedure. The question asked was "how much fear/distress did you/your child/the child experience when the needle was inserted?" (range 0-100). Cortisol serum levels were also taken at the time of needle insertion and after 30 minutes. The mean VAS scores reported by the children were 16 in the paracetamol group and 27 in the control group. The mean VAS scores reported by the parents were 31 in the paracetamol group and 19 in the control group. The mean VAS scores reported by the nurses were 33 in the paracetamol group and 28 in the control group. The authors accepted a reasonable effect measurement of 15 (mm) according to previous studies on the use of VAS for pain. The serum cortisol levels were found to be reduced on average 20mmol/L in the paracetamol group, and 26mmol/L in the placebo group. Cortisol does not increase for a period of around 30 minutes after fear is felt – the authors acknowledged that the first sample therefore was not a baseline score, but more likely to represent the fear felt near the beginning of the procedure. The authors concluded that paracetamol does not add any beneficial effect to the reduction of pain or fear in this cohort of children when combined with topical anaesthetic.

In contrast to pharmacological analgesics, other methods have also been assessed in the literature, such as cold spray and ice, the subject of Çelik and Düzükaya's recent paper (2024). They assessed the effect of two non-pharmacological analgesics – cold spray and ice – on children having venepuncture in the paediatric emergency unit of a Training and Research Hospital in Turkey. Children aged between seven and 15 years were eligible for inclusion. A total of 96 children (45 girls and 51 boys) were included in the study, and were randomised to routine care, cold spray or ice during their procedure. A sample size calculation aiming to achieve 0.8 power and 0.05 type 1 error identified that 90 patients would be required. The child, parent and a researcher were asked to complete the Children's Fear Scale (CFS) for anxiety and Visual Analog Scale (VAS) for pain before, during and after the procedure. There was no reference to blinding, and the precise timing of the measurement collection was not recorded. Only the pre- and post-intervention scores are reported. The research team reported that the control group had lower pre-intervention pain scores than the other groups. They reported a statistically significant difference between the groups in post- and pre-intervention pain scores, with the scores increasing in the control group, and decreasing in the others.

The largest decrease was observed in the spray group. The control group also reported lower levels of pre-procedural anxiety. There was a statistically significant difference between the groups in relation to the pre- and post-procedural fear scores, with the control group increasing (2.91 to 3.81) and the ice (3.71 to 3.31) and cold spray (4.09 to 1.78) decreasing with the spray group again showing the highest change. The authors acknowledged that their study was based on a small sample having a specific procedure, and that the lack of blinding could have influenced the results. They also considered the lack of evidence for the use of these techniques, meaning there were limited references for comparison. They concluded that cold spray is more effective than ice or normal care for the management of anxiety and pain in this age group during venepuncture. They suggested that further research should focus on a wider population and larger age range.

The limitations common to both Hedén, von Essen, and Ljungman studies were that there was a single timepoint for the measurement of needle fear, meaning that conclusions cannot be drawn regarding reduction or change, and that there was a delay in seeking a post-treatment score meaning the responses may not be truly reflective. Furthermore, the study may not have been adequately powered due to the lack of a sample size calculation. Limitations common to all three studies included the participant populations, which were insufficient to generalise to a wider population, and lack of screening during recruitment, meaning none of these interventions were specifically tested in populations with a known fear of needles.

Preparation

Preparation prior to a NBP could include discussions about what will happen in child appropriate language, information leaflets (Heaton *et al.*, 2013) using play to simulate the procedure (Kajikawa, Maeno, and Maeno., 2014), or attending introductory sessions in the hospital to see what happens to blood samples. The literature on the effectiveness of such preparation is limited.

Birnie and colleagues included four trials in their Cochrane review which assessed preparation vs either standard care or an alternative treatment. Very low-quality evidence (4313 participants) showed no effect for preparation or information on distress related to NBPs (Birnie *et al.*, 2018).

A computer assisted relaxation technique (CARL), described in detail in the section on relaxation above, also included information leaflets, in order to prepare the patient for treatment. The authors concluded that the relaxation learning was superior in reducing anxiety (Heaton *et al.*, 2013).

In contrast to written formats, young people could be engaged in learning through play. Japanese researchers assessed the success of play preparation on the self-reported needle fear of healthy children in four children's centres in Japan (Kajikawa, Maeno, and Maeno., 2014). A total of 191 children (94 girls and 79 boys) attended an event where they learned about injections and vaccines before 'injecting' a vaccine of water into pretend skin (sponge) with an imitation needle. Children were asked to record their level of fear of needles on a four-point Likert scale before and after taking part in the session. The number of children who reported a fear of needles before the event (69) decreased after taking part (51), and those unwilling to be vaccinated (48) also decreased (27). The authors found that children who reported a fear of needles were more likely to also report that they would refuse vaccination (36 vs 12). The number of needle-fearing children who would refuse vaccination decreased after the event (36 to 19). The limitation of this study was that this sample of children's results may not be generalisable to other populations.

A health information app which was developed for young people with needle fear called Xploro underwent feasibility testing which was reported in a recent paper by Bray and colleagues (2024), who considered its use in preparation for blood sampling. They were both investigating a preparation intervention for young people with needle fear undergoing blood sampling and assessing its acceptability to children, parents, and healthcare providers. The Xploro app is a health information platform containing models of the real-life environment, and an interactive experience showing what happens during a blood test. Xploro also describes a breathing relaxation technique that can be used. The authors of this study recruited children between (six to 14 years old) over three months. These participants were recruited prior to their attendance in the clinical setting through telephone contact and provision of the app, completing their consent when they attended for their blood test. Children were asked to complete study questionnaires before and after their blood test, and it was recorded whether their procedure was successful. The researchers do not state a target sample size, but contacted 47 families, 24 of whom agreed to participate (51%). Of those 24, 20 completed both questionnaires (83.3%). The participants who did not complete their follow-up questionnaire are reported to have been too upset after their procedure. The writers concluded that the app is acceptable based on the feedback from the stakeholders. They acknowledged that their sample was small, and a convenience sample of interested patients attending a clinic – meaning that the parents who agreed may have been predisposed to give positive feedback, as they were engaged with preparing their child for the procedure. No demographic information was recorded, so it is unclear if the sample would be representative of the general population.

It was also felt that participants may have been under pressure to provide the 'right' answers to the team as they handed back their questionnaires immediately after the procedure, meaning they may have worried about anonymity. The authors concluded that Xploro is useful and engaging, and that parents also benefited from understanding their child's procedure.

Preparation appears to be a reasonable and easy method of helping children to understand the reasoning behind, and process of NBP. It could be beneficial to children who seek information to reduce anxiety, although the quality of evidence to support this is very low.

Support and distraction

A systematic review assessing the overall literature on distraction interventions for needle-related pain and distress in children was published in 2021 by Cho and Choi (2021). They defined a distraction intervention as 'a cognitive or behavioural strategy to relieve pain, stress and anxiety by distracting children from a harmful stimulus'. The aim of the review was to compare and analyse the effectiveness of different interventions on needle-related pain and distress in children. Only studies which were published in English, reported outcomes for children, compared an intervention with normal care and had a randomised controlled trial (RCT) or quasi-experimental design were suitable for inclusion. After screening, 45 articles were identified as suitable and included in the analysis. Studies were published between 2011 and 2018, with 41 RCT designs and four quasi-experimental designs. The authors reported that 15 studies included observer anxiety scores, while three included child reported scores. They found a medium effect level (-0.68) in the studies with parental measurement of anxiety, and a high effect level (-1.03) where a nurse had completed the measure. They did not report effect sizes for self-reported anxiety. They acknowledged that the review has limitations common to meta-analyses – difficulty including unpublished works and identifying all relevant literature for inclusion. The exclusion of studies not published in English could also have affected the outcome of the review. The results were difficult to generalise due to the narrow scope of the included studies, and it was noted that most studies focused on younger children. No cost-effectiveness analysis had been completed in any of the identified works and therefore the authors could not assert whether these methods are cost or time effective. They concluded that while distraction techniques are effective in the reduction of needle-related pain and distress in children, further research is required to improve the evidence base.

Many studies have since compared or assessed methods of distraction for children with needle fear including animals (Abdullah and Suat., 2024); toys (Erdogan and Aytekin., 2021; Özkan and Polat., 2020; Arikan and Esenay., 2020), Virtual Reality (VR); (Aydos et al., 2024; Gerçeker, Bektaş and Yardımcı., 2024; Kirbaş and Kahrıman.,2024 Savaş, Semerci,. and Bayram, C., 2024; Niaz et al., 2023; Gao et al.,2022; Lluesma-Vidal et al., 2022; Wang, Guo, and Xiong., 2022; Czech et al.,2021) and sensory distraction devices (Düzkaaya et al., 2024; Oluc and Arslan.,2024; Semerci, Akarsu and Kiliç., 2023; Erdogan and Aytekin., 2021). Sensory distraction devices have included methods such as blowing soap bubbles, squeezing balls, or use of sensory devices such as the Buzzy® or ShotBlocker® tool to distract the children during their procedure These methods are discussed in turn below.

Animals

A recently published work investigated whether the presence of aquatic animals (goldfish and turtles) could reduce the pain, fear and anxiety of children undergoing intravenous catheterisation (Abdullah and Suat., 2023). The study recruited and randomised 90 children aged between five and six years old from a hospital service in Turkey. The effect size for the sample was calculated as 0.3. Each child was randomised into either the control group, fish, or turtle group. The animals were present in tanks during the procedure and were not handled by the children. The families were asked to complete three measures before, during and after treatment – the Wong Baker Faces scale, Children’s Fear Scale (CFS) and Children’s State Anxiety (CSA). Due to issues obtaining the results during treatment, this measurement was in fact taken ten minutes after the procedure. These measures were completed by the child, their mother, and a researcher. The authors determined that there was no significant difference between the fear scores (CFS) of the three groups at baseline but a significant difference between the animal and control groups ‘during’ and after the procedure, with the animal groups having lower scores ($p < 0.05$). The authors concluded that the presence of fish or turtles decreased the pain, anxiety, and fear in children during cannula insertion. They acknowledged that the study had been completed with a limited age range in a single site. The limitations specific to this study were the timepoints of the second measurement, which meant it could not be determined whether the reduction in pain, anxiety or fear was caused by the animal distraction, or the natural resolution of these following completion of the procedure.

Toys

Different forms of toys have also been evaluated in the literature for their effectiveness as distraction tools during NBPs. In Özkan and Polat's work, they compared a kaleidoscope toy with virtual reality (VR) distraction. They aimed to compare the effects of both distraction techniques on fear during venepuncture in 4–10-year-old children attending in the phlebotomy service of a hospital in Turkey (Özkan and Polat., 2020). A target sample size of 150 was calculated based on the findings of an earlier study of VR use in needle anxiety by Piskorz and Czub in 2018, with power of 0.8, an alpha rate of 0.05 and an effect size of $d=0.839$. In the study 135 children aged 4- to 10-years-old (90 girls and 45 boys) were recruited and randomised to receive either VR distraction, kaleidoscope distraction or standard care. There was no assessment during the recruitment process to identify whether participants had needle fear or phobia. Children, their parents and two observers were asked to complete the CFS prior to their procedure, and after venepuncture was completed. The exact timings and question asked are not described. The differences between the reported scores between groups was not found to be statistically significant. The differences between the mean scores between reporters was statistically significant ($p = 0.000$). The post-procedural scores were lower in the distraction groups than in the control group for all reporters. When comparing the post-procedure results between the kaleidoscope, control and VR groups, the anxiety scores for the kaleidoscope group are lower than the control, and the VR groups are lower than the kaleidoscope group. These results were found to be statistically significant ($P=0.000$). The authors concluded that VR goggles are more effective than kaleidoscope distraction in this cohort, and that further studies should be completed in other cultures and different age groups to assess the effect in different cohorts.

Another form of toy distraction which has been investigated, is the use of distraction cards. This was compared to both sensory and virtual reality distraction methods in a study by Erdogan and Aytakin (2021). The sensory distraction was provided by a healthcare tool called Buzzy®. Buzzy® is a small bee shaped device with a detachable icepack, which can be applied to the skin. The device vibrates, as well as providing optional cold stimulus through the icepack, and is used on an area adjacent to the site of the procedure. The study included children aged 7-12 undergoing phlebotomy in the venepuncture unit of a university hospital in Western Turkey (Erdogan and Aytakin., 2021). Three different distractions were used: distraction cards, virtual reality, the Buzzy® device and a control group. Overall, 160 children were recruited. A power analysis was then performed to clarify if this sample size was sufficient to detect a power of 98% and an effect size of 0.4, alongside a type 1 alpha rate of 0.05. This determined that the original sample of 160

participants was a large enough sample to detect significant differences. Eighteen children did not complete the study due to withdrawal, or a failure to complete treatment at the first attempt, leaving a final sample of 142 (72 girls and 70 boys). Block randomisation was used to allocate children to each group, using the variables of age (7-9 or 10-12), sex and fear of procedure (yes or no) to ensure an even spread in each group. The exact question for determining fear of procedure is not reported. The study could not be blinded due to the obvious nature of the intervention. Approximately half of the children in each group responded 'yes' to fear of procedure (range 47.1% - 54.3%). The children were asked to complete the CFS to score their anxiety immediately after their procedure, alongside one parent and a research nurse. There is no reported pre-procedure score, or which precise question was posed to the participants when asking them to complete their scores. The mean post-procedure CSF scores were 2.0 for the control group, 1.2 for the distraction card group, 0.7 for the virtual reality group and 0.5 for the Buzzy® group. The effect size for the CFS self-report scores was $\eta^2=0.255$, which was a medium effect size. The authors stated that their study confirms previous findings that all three distraction methods appear to reduce pain and fear in children undergoing phlebotomy procedures. The limitations of this study were the poor reporting of the procedure when measuring the needle fear of the children and the lack of measurement of pre-procedural anxiety limiting the assessment possible.

Another method of distraction which has been evaluated with children is the use of traditional toys. Arikan and Esenay investigated differences in effectiveness between active and passive distraction with toys (2023). They focused on children aged between 6-12 years old in a paediatric emergency department in Central Turkey, using a toy wristband for passive distraction and a wooden rotary toy for active distraction. They aimed to assess for any reduction in pain, fear, and anxiety during NBPs (Arikan and Esenay., 2020). A power analysis calculation was undertaken with a power of 0.95, effect size of 30% and alpha level of 5% which dictated a sample size requirement of 216 children. In total, 216 children (108 girls and 108 boys) were recruited and randomised to receive either standard care, active distraction with a rotary wooden toy or passive distraction with a toy wristband. The study could not be blinded due to the obvious nature of the intervention. It is reported that 50% of the children had 'fear of blood sampling'. The method by which this assessment was made is not reported. The CFS was used to assess self-reported and observer-reported anxiety before and during the venepuncture procedure. It is not reported which precise question was posed to the participants when asking them to complete their scores. Children in the control group reported an increase in mean fear during venepuncture while children in the active and passive distraction groups reported a decrease in mean fear.

Parent observers in the control group also reported an increase in mean fear of the children during venepuncture while in the active and passive distraction groups they reported a decrease in fear. Researcher observers in the control group reported a similar increase in mean fear of the children during venepuncture while in the active and passive distraction groups they reported a decrease in fear. The difference in the mean scores of all groups prior to venepuncture was not statistically significant ($p > 0.05$). The difference in the mean scores measured during venepuncture was found to be statistically significant ($p < 0.05$). The active distraction group reported the lowest scores, followed by passive distraction and control. There was no statistically significant difference between the rater's scores (children, parents, and researchers). The authors concluded that both active and passive forms of distraction are feasible options for reducing fear during paediatric blood sampling. The limitations specific to this study included the failure to differentiate between the results for the needle phobic cohort vs the non-needle phobic cohort.

Virtual reality

Virtual reality is defined by Britannica as 'the use of computer modelling and simulation that enables a person to interact with an artificial three-dimensional (3D) visual or other sensory environment'. Czech and colleagues published their systematic review assessing virtual reality (VR) interventions for needle-related fear, pain, and anxiety in July 2021. They aimed to analyse and synthesise the existing evidence on the effectiveness of VR interventions on the prevention of fear, pain, and anxiety during needle-related procedures on children. The authors included papers published in Polish, English or Italian, where children were included and reported and only studies with a randomised controlled trial (RCT) design. They included available grey literature. After screening, seven studies were included in the review. Of the seven studies included, four could be analysed for fear symptoms. The studies had each used a different scale for measurement, and the authors attempted to analyse a standardised mean difference with random model effect. However, the studies were too heterogenous to be pooled. Only two of the included studies could be analysed for anxiety symptoms, although these had both used the same scale (Children's Anxiety Meter – CAM). Unfortunately, these studies were also too heterogenous to be pooled. The authors acknowledged several limitations to the review, which included the low number of studies and difficulty accessing the full results of each paper, meaning clinical importance could not be qualified. It was also difficult for the authors to complete their analyses due to the high heterogeneity of the studies, which they reported could be due to the differences in treatment being performed. They concluded that VR distraction has the potential to be an effective tool in the management of paediatric needle-related fear and anxiety, but that further research on larger groups with similar conditions is needed to provide higher quality evidence.

An additional limitation to this study was the lack of a common measurement scale for needle related fear or anxiety, making direct comparisons between studies more challenging.

Following on from this review, several other systematic reviews investigating the use of VR in the management of paediatric needle fear have been completed, discussed in turn below.

In April 2022, as a follow-up to the Czech and colleagues review above, Wang, Guo and Xiong published their systematic review, which stated that the original review had failed to demonstrate an advantage of VR (2022). This was due to the seven included studies being too heterogenous to be pooled. The authors aimed to re-examine the effects of VR on needle-related pain, anxiety and fear in children and adolescents. Studies were eligible for inclusion where the patients had been aged under 21 (whereas Czech *et al* included children up to the age of 18), there was a randomised controlled trial (RCT) design, and the text was published in English. They did not include grey literature. After screening, ten studies were included which had been published between 2006 and 2021. Of the ten studies included, five had utilised the same measurement scale for fear (Children's Fear Scale – CFS) and were included in the analysis. The authors reported that these studies showed that the use of VR compared to a control resulted in reduction of needle fear regardless of whether the measure was completed by children (WMD -1.52), parents (WMD -2.3) nurses (WMD -1.55), or third-party observers (WMD -0.59). The authors were able to assess anxiety results in seven of the 10 studies, reporting that VR also reduced anxiety compared to control when reported by children (WMD -2.79), parents (WMD -3.87), nurses (WMD -4.64) or third-party observers (WMD -2.06). There was reported heterogeneity in all analyses.

The authors acknowledged some limitations to the review including the difficulty eliminating all heterogeneity (even using random model effects to limit the impact), the included studies being unblinded, the possibility of selection bias for participants recruited and the fact that the review and meta-analysis was not registered and reviewed prior to completion. They concluded that a VR intervention could reduce needle-related pain, anxiety and fear in children and adolescents and did not make any recommendations for future research. The outcome of this review, although it did include meta-analysis of fear and anxiety outcomes, mirrors the original Czech and colleagues review on which they had hoped to improve.

In August of the same year the final version of Lluesma-Vidal and colleagues' systematic review was published. A pre-print version was originally accepted in November 2021, just 4 months subsequent to the Czech *et al* review.

The authors aimed to collect and analyse the current evidence investigating the use of VR as a distraction from needle related pain and fear in children. The authors included studies with participants under the age of 21 (compared with under the age of 18 in the Czech paper), where the study design was an RCT or quasi-RCT and where the main outcome measure was pain. This differs significantly from the other systematic reviews which focused on anxiety and fear equal to pain. There were no language restrictions. Following screening, 21 papers were included in the review, with 10 being suitable for meta-analysis. The studies were published between 2002 and 2021. Only five of the included studies could be investigated for fear. The authors reported that the global effect of using VR significantly reduced the fear of children (IV -1.26). The authors acknowledged that there were some limitations to their review, which included the possibility that some literature had not been identified for inclusion. Similarly to other reviews, the heterogeneity of the studies made analysis difficult and means the results may not be interpreted correctly. They identified a lack of studies in children under four years old. The authors concluded that VR could be a feasible method for reducing fear and pain in children during needle procedures and recommended that future work focuses on larger sample sizes with higher quality methodological techniques.

A final review was published in November 2022 by Gao and colleagues, who registered their protocol on PROSPERO in April of the same year (ten months after publication of the review by Czech and colleagues in 2021). The aim of the review was to evaluate the pain, anxiety and fear in paediatric patients undergoing needle-related procedures. Studies were included where they included patients under the age of 21, had an RCT design and were published in either English or a Chinese language. After screening, 27 studies were identified for inclusion, published between 2006 and 2021. Anxiety data were available in ten of the 27 studies, with a reported statistically significant difference in scores in the VR groups (SMD -0.61). Fear data were available in seven studies, with a reported significant difference in the VR groups (MD -0.81). The authors suggested that the limitations of their review included limiting the publication languages to Chinese and English, introducing a potential publication bias. They noted that the intervention could not be blinded due to its nature, which could influence the results of studies. They also considered that the small number of RCTs available for inclusion may have influenced the overall results. Similarly to the other reviews, the authors recommended the use of VR in this patient group as a potentially beneficial intervention, and suggested future research should include larger sample sizes and higher quality design.

These four reviews all posed a similar research question and should reasonably have identified a similar cohort of studies. They were all published within a 15-month period, with only one having published their protocol in advance.

No conclusive additional evidence was gained through a second, third or fourth review, likely as the literature searches were all completed in a similar period. Only one of the later reviews referenced an earlier review (Wang referencing Czech) suggesting that the others were either unaware of the earlier publications, or deliberately excluded them from their discussions. The publication of a protocol in advance not only allows for peer review, which can lead to suggested improvements, but should theoretically prevent such repetition of research activity.

Since the publication of the four reviews described above, one further systematic review and several additional studies have been published investigating VR in the management of paediatric needle fear. The further identified systematic review was published in 2023, which contained 11 papers and did not reveal any novel conclusions (Niaz *et al.*,2023). A selection of additional studies is described below.

A virtual reality biofeedback game named 'Golden Breath' was the subject of a paper published by Aydos and colleagues in 2024. The study took place in a university hospital in Turkey, and evaluated the feasibility, acceptability, and safety of this newly developed game. The study was conducted with children aged between four and 12 years old. The authors referred to 'guidance for pilot studies' and based their sample size on the study undertaken by Savaş, Semerci, and Bayram (described above). The authors did not explicitly state the target sample size but advised that 11 participants (seven girls and four boys) were recruited. The VR intervention in this study, Golden Breath, is a biofeedback game used alongside a VR headset, wired microphone and smartphone app. The microphone is used to monitor the breathing rate, which interacts with gameplay. Children were asked to complete two anxiety measures – the Children's Fear Scale (CFS) and the Child Anxiety Scale-State (CASS) before and after the procedure, alongside satisfaction and acceptability measures. There was no explicit statement of the timings the measures were completed. The authors reported that there was a statistically significant decrease in the mean fear scales reported (5.18 to 2.27), although it is not clarified if these are based on the CFS, CASS or some combination of both. The authors acknowledged several limitations to their study, most notably that the sample was small and in a single setting, which limits the generalisability of findings. There is no control group in the study, which limits the conclusions which can be drawn from the findings. The authors suggested that future research should aim to address these limitations through the inclusion of larger sample sizes and a more diverse population, with control groups as a comparator. They concluded that based on this study, Golden Breath is a feasible, safe, and acceptable intervention for use during paediatric needle procedures.

Another biofeedback game (similar in basis to Golden Breath described above) was investigated in a study also published by Turkish researchers. Savaş, Semerci, and

Bayram investigated whether the biofeedback-based VR game could impact the pain, fear, and anxiety levels of paediatric oncology patients undergoing port needle insertion (2024). The study took place in the paediatric haematology and oncology unit of a Turkish city hospital with children aged six to 12 years old. The target sample size was 52, based on a sample size calculation to achieve 90% power and 95% confidence level. Overall, 62 patients (30 girls and 32 boys) were recruited and randomised to receive either the VR intervention or a control group. The VR intervention involved choosing a game (either submarine or garden) which could then be interacted with through breathing control. Each environment was populated with more content as the user breathes slowly and regularly. Breathing was measured through a sensor worn on the user's chest. In this study, the sensor was applied two minutes prior to the procedure. Children and their mothers were asked to complete four outcome measures: the Wong Baker FACES pain scale, the Children's Fear Scale (CFS), the Child Anxiety Scale-State (CASS) and a Visual Analog Scale for satisfaction (VASS). These scales were completed prior to the procedure, and three minutes after the procedure. The respiratory rate was also measured using the VR sensor. The authors reported that both groups had similar pre-procedural self-reported (2.62 and 2.83), and proxy-reported (2.71 and 2.83) fear scores. Post procedure mean fear scores were shown to be significantly lower in the VR group (1.46 self-report, 1.62 proxy report) than the control group (2.8 self-report, 2.87 proxy report). The authors also reported that both groups had similar pre-procedural self-reported (5.12 and 5.48), and proxy-reported (5.28 and 5.45) anxiety scores. Post procedure mean anxiety scores were shown to be significantly lower in the VR group (2.57 self-report, 2.59 proxy report) than the control group (5.38 self-report, 5.45 proxy report). The mean respiratory rates per minute were lower in the treatment than control group. All these findings were reported to be statistically significant ($p < 0.001$). The authors acknowledged that there were limitations to their study including the inability to blind the participant and researcher, the potential interaction between the study groups and the fact that some children would have greater previous experience of the procedure than others. The authors concluded that this VR intervention reduces anxiety and fear related to port catheter insertion in this cohort.

Sensory distraction

Sensory distractions were one of the techniques included in a 2018 Cochrane review analysing psychological interventions for the management of needle fear and pain (Birnie *et al.*, 2018). Of the 59 trials included, 32 investigated distractions compared to standard care or alternative treatment. Any study with five or more participants in each arm was eligible for inclusion.

Very low to low quality evidence supported the efficacy of distraction in reducing self-reported distress (four papers, 426 participants, SMD -0.62), observer-reported distress (five papers, 1067 participants, SMD -0.72) and behavioural distress (seven papers, 500 participants, SMD -0.44). This suggests that sensory distraction may be beneficial for the management of needle fear, although the existing evidence base is weak and could be improved.

To further explore the benefit of sensory distraction, Semerci, Akarsu and Kiliç (2023) assessed the effect of Buzzy®, a vibration device, compared to cold spray or normal care in the management of pain, anxiety and fear of children having venepuncture in a paediatric emergency department in Turkey. Overall, 180 children aged five to 12 years (78 girls and 73 boys) were recruited and randomised, with 161 completing the study. There was no reference to blinding. A sample size calculation aiming to ensure 80% power and 5% type 1 error rate determined that 159 children would be required. All children, parents and the treating nurse were asked to complete three measures after treatment was complete – the Wong-Baker Facial Expression Rating Scale (Wong and Baker., 1988), the Child Anxiety Statement Scale (CAS-S – Ersig *et al.*, 2013) and the Child Fear Inventory (mistitled of the Children’s Fear Scale - CFS). The results indicated a statistically significant difference between the post treatment pain score, with the control group having the highest mean, followed by the Buzzy® and then cold spray groups ($p < 0.001$). The anxiety scores were also shown to have statistically significant differences, with the control group again having the highest mean score, with the Buzzy® and cold spray groups having similar scores ($p < 0.001$). The fear scores similarly revealed highest scores in the control group, with the Buzzy® and cold spray groups having similar scores ($p < 0.001$). The authors acknowledged that the study had been completed in a single centre, limiting its generalisability, and that as it was not blinded, this may have influenced the scores. They asserted that the Buzzy® tool and cold spray were more effective than standard care in the reduction of pain, anxiety, and fear in this cohort. The specific additional limitation of this study was the single timepoint for measurement, meaning it cannot be ascertained if there was any change in needle fear due to the intervention.

Another sensory tool proposed to provide sensory distraction during NBPs is ShotBlocker®. The ShotBlocker® is a device shaped like a horseshoe, with short 2mm projections which can be applied to the skin, with a hole in the middle to allow access for injections. The device is used to apply pressure to skin during the procedure. Düzkaya and colleagues assessed the impact of ShotBlocker® compared with the Helfer skin tap technique on the pain and fear experienced by six to 12-year-old children during intramuscular injections (2024). The study was undertaken in the paediatric emergency department of Tarsus State Hospital in Turkey.

A sample size calculation was completed with the aim of achieving a power of 80% and type 1 error of 0.05, which determined that 177 participants would be required. The team recruited the required 177 patients (92 girls and 85 boys) who were randomised to either the ShotBlocker® (SBR), Helfer skin tap (HST) or control group. The children, their parents and an observer were asked to complete two measures both before and after the procedure – the Wong Baker FACES pain scale and the Children’s Fear Scale (CFS). The authors reported that mean scores for the CFS were not statistically different between groups at baseline. In the control group the mean CFS scores reported by children (2.68 pre, 3.34 post), for parents (2.49 pre, 2.9 post) and the observer (2.22 pre, 2.93 post) increased post-treatment. For the HST group, the mean scores reported by children stayed the same (2.97 pre and post), while parents (2.56 pre, 2.19 post) and observer (2.71 pre, post 2.61) reported means decreased. In the SBR group, decreased mean scores were reported by children (2.9 pre, 2.56 post), parents (2.56 pre, 2.19 post) and observers (2.58 pre, 2.24 post). The authors acknowledged that there may be other reasons for the scores depending on the patient background.

They considered that the small population studied limited the generalisability of the findings. Unfortunately, there was a natural disaster in the area which limited data collection as the hospital closed the study to focus on treating affected victims. The authors concluded that the ShotBlocker® was the most effective method of reducing pain and anxiety for children undergoing intramuscular injections.

More recently, Oluc and Fatma (2024) investigated the effect of distraction through blowing soap bubbles or squeezing a ball on the fear and pain of children aged six to 12 years undergoing venepuncture at in a hospital in Turkey. They recruited and randomised 111 children (56 girls and 55 boys) to receive either standard care, soap bubble blowing (SBB) or ball squeezing (BS) during their procedure. Due to the obvious nature of the different distractions, the study could not be blinded. There is no reference to why this sample size was chosen. Children, parents, and a nurse observer were asked to complete two scales pre and post procedure – the Children’s Fear Scale (CFS) and the Wong Baker FACES pain scale (WB-FACES). It is not stated exactly when pre and post procedure these were completed, or what question was posed with the CFS. The CFS is also designed for self-report rather than proxy use. The results indicated that there were ‘significant differences’ between the pre-procedural fear levels reported by parents and children between the groups ($p < 0.005$), however on review it appears that these numerical differences are very small and therefore may not be clinically relevant which is not stated in the paper. The authors report that there was a significant difference between the pain reported by researchers, children, and parents between groups, with the pain scores in the SBB and BS groups lower than the control group ($p < 0.005$).

The pain scores presented are assumed to be post-treatment although this is not explicitly stated. Fear scores were also reported to differ, with the SBB group having lower levels of fear than the BS and control group ($p < 0.05$). The researchers also noted that there was a statistically significant difference between the scores provided by the child vs the parent, which is in keeping with the wider literature. They did not detail why they had chosen to include proxy reporting measures.

The authors concluded that SBB and BS reduced pain during invasive procedures and that SBB is most effective in the management of fear. They acknowledged a limitation was their use of self-report measures, although they did not further quantify this statement and it was unclear why they drew this conclusion. The limitations specific to this study were the lack of justification for the sample size and the reliance on proxy reporting to supplement the use of more reliable self-report measures.

All forms of distraction appear to have merit in the reduction of paediatric anxiety during NBPs. Emerging evidence suggests that VR may be more effective than standard techniques. VR technology requires special equipment, appropriately designed programmes, and software, which require maintenance and updating over time, making them more resource intensive than some other forms of distraction. It has the potential for future design to be customisable for the individual patient and/or procedure. The evidence base for distraction techniques is moderate quality however, except for VR, the studies tend to focus on younger children with a paucity of literature on the effectiveness of these techniques for adolescents.

The limitations common to both studies are the participant populations, which are insufficient to generalise to a wider population, and lack of screening during recruitment, meaning none of these interventions were specifically tested in populations with a known fear of needles.

Hypnosis

Hypnosis is defined by the American Psychological Association as 'a therapeutic technique in which clinicians make suggestions to individuals who have undergone a procedure designed to relax them and focus their minds'. It has been described for use with children as early as the 19th century, in Baldwin's 1891 paper 'Suggestion in Infancy'. Kohen and Kaiser defined clinical paediatric hypnosis as 'a tool to facilitate the evolution and refinement of self-regulation skills and capacities' in their 2014 paper, which describes the broad range of potential applications (Kohen and Kaiser., 2014). The literature suggests that children are most suggestible to hypnosis between the ages of nine -12 years old (Morgan and Hilgard, 1973), although there is no specific contraindication in its use in younger children.

Hypnosis has been identified by Birnie's recent 2018 Cochrane Review as a psychological technique being used for the management of needle fear in children, although the literature to support this is limited. Birnie and colleagues' 2018 review focused on psychological interventions for needle-related pain and distress in both children and adults. As previously discussed, all peer reviewed RCTs with at least five participants in each arm were eligible for inclusion if they compared a psychological intervention to standard care or a comparative treatment. 59 trials were included in total, with 5550 participants, eight papers were identified which assessed hypnosis. Very low-quality evidence suggested that hypnosis is effective in reducing self-reported distress (five papers, 176 participants, SMD -1.4) and behavioural distress (six papers, 193 participants, SMD -1.15). Only one study assessed observer-reported distress (Birnie *et al.*, 2018).

Hypnosis may have potential as a tool to aid children in managing their fear during NBPs, although there is poor evidence for the technique. It is used in the management of a variety of conditions, including anxiety disorders and specific fears as described by Kohen and Kaiser (2014). Hypnosis treatment requires an engaged and willing patient and parent, and a trained professional to be present (at least for initial introduction and training in the technique), which may necessitate a referral prior to the planned treatment.

2.3.2 Techniques to address unhelpful thoughts and feelings

Graded exposure

Graded exposure is a treatment which was developed to help patients manage fears that present in mental health settings (Edelmann., 1995; Emmelkamp *et al.*, 1992). It can be approached in different ways, some of which can be completed by a person without external help. It is also sometimes referred to as 'desensitisation'. There is a real paucity of evidence assessing the use of exposure for the management of needle fear in children.

McMurtry and colleagues reviewed one paper by Ost, Fellenius, and Sterner as part of their 2015 systematic review which investigated ATT alongside graded exposure. The paper is described in more detail in the section on ATT above. Participants were given treatment over 5 weeks which included hierarchical exposure (gradually exposing oneself to more anxiety inducing activities relevant to the procedure). The exposure-based therapy group showed benefit post-treatment but not at their 1 year follow up, suggesting the effect was temporary (McMurtry *et al.*, 2015; Ost,

Fellenius, and Sterner., 1991). McMurtry and colleagues also published a suggested clinical guideline and called for future research in relation to exposure-based therapy for needle fear (McMurtry *et al.*, 2016). They recommended in vivo exposure therapy compared to no treatment for children aged seven and older, stating that this recommendation was strong but based on indirect evidence as there are no published studies on the effect of exposure therapy for needle fear. Taylor and Campbell promoted the use of needle desensitisation for intra-oral injection fear in paediatric patients in their 2011 paper describing the technique. The authors recommend this is combined with a relaxation technique (Taylor and Campbell., 2015).

A further systematic review of exposure-based treatments for fear and reactivity to medical procedures was published in 2024 (Abdel-Jalil, Baldwin and Leaf). The aim of the paper was to review literature from 1955 – 2021 where exposure treatments were used in the management of fears in any medical procedure. Papers were included where the participants demonstrated a phobia, or avoidance, of a medical procedure and where the publication was in English and excluded if they were systematic reviews or commentaries. The authors identified 62 papers (715 total participants) which were eligible for inclusion, published between 1968 and 2021. A small percentage of the studies included children (14 studies) while one did not report the age of the participants at all. Therapy had been applied to 11 different medical procedures including two needle-based procedures – injections (eight studies) and blood sampling (12 studies). Many of the studies which included children were dental studies (seven studies) with only one focusing on an NBP (injection). The authors reported that the number of sessions varied between studies with some providing a single session, up to 161 sessions. They found that most studies included between one and 30 sessions, and that where more than 30 sessions had been provided, the participants in the study were predominantly neurodivergent, with autism being the most common neurodiversity. Most of the included studies had combined exposure therapy with an additional technique (87%).

The authors also investigated ‘terminal behavioural outcomes’ reported within the studies, which included outcomes such as whether the participant continued to require sedation or restraint, managed a simulated procedure or whether the treatment was successfully completed. Overall, 41 studies reported that their participants had met the terminal behavioural outcome, 18 reported partially met outcomes and two did not report this data. A variety of additional participant outcome measures were used within the studies including self-reported anxiety scales, behavioural observation, and physiological measures.

Paediatric studies included in this review included only terminal outcome and observational measures. The authors reflected that a general downward trend had been shown in number of publications, with more than half (32) of the articles having been published prior to 1986. They suggested this may have been due to the relative novelty of the technique at the time. The authors also made recommendations for future research including conduction of assessments prior to treatment to verify phobia or reactive condition; more clarity on treatment being provided; a wider range of populations particularly paediatric and neurodivergent groups; and investigation of exposure as a standalone treatment. They acknowledged some limitations to the review. The first limitation was reported to be difficulty to assessing the presence of neurodiverse participants, unless the paper reported this specifically. The search terminology may also have excluded relevant papers if the intervention had been described in other terms. The absence of a meta-analysis also does not enable comparison of results or clarity of the quality of the current evidence. This review highlighted the ongoing lack of evidence for this treatment across the board, not just limited to evidence for management of needle fear in children.

Graded exposure has potential for use as a treatment for needle fear, having been shown to work with other specific phobias. It could help individuals to manage their unhelpful feelings and physical symptoms related to needles but would not work to help them address their unhelpful thoughts. There is no current evidence to support its effectiveness in patients with needle fear.

Cognitive behavioural therapy

Cognitive behavioural therapy (CBT) is a psychological therapy which is described by NHS England as a ‘therapy that helps individuals by addressing the way they think and behave (NHS UK 2021). Fenn and Byrne explain that CBT explores the link between an individual’s thoughts, emotions, and behaviours in response to situations or scenarios (Fenn and Byrne., 2013) . It can only be used once an individual has the cognitive ability to understand and appreciate these thoughts and their associations, this has shown to occur at age seven according to Piaget’s theory (Piaget., 1964). CBT fulfils the criteria for a well-established and empirically supported therapy as its efficacy has been established by two or more methodologically reliable randomised controlled trials, as described by Meyer and Scott (2008). CBT can be delivered in self-help, guided self-help, and electronic formats as well as traditional delivery by a psychologist or other trained healthcare professional.

There are many models of CBT, including the Five Areas model proposed by Williams and Garland in 2002. The Five Areas Model focuses on exploring five interrelated topics:

1. Life situation, relationships, and practical problems
2. Altered thinking
3. Altered emotions/feelings
4. Altered physical symptoms
5. Altered behaviour

This model can be tailored for use in individual scenarios, such as the model adapted to dental anxiety (appendix 3).

Cognitive behavioural therapy (CBT) was identified as a treatment for needle fear in the systematic review of interventions for children with high levels of needle fear by McMurry and colleagues in 2015. The evidence base for treatment with CBT for anxiety disorders and specific phobias in children and adolescents is currently low (James *et al.*, 2020) and there are limited studies investigating its effectiveness in the management of needle fear (Berge *et al.*, 2017; Vika *et al.*, 2008).

Birnie and colleagues undertook a Cochrane systematic review of psychological interventions for needle-related procedural pain and distress in children and adults in 2018. They identified 18 studies which assessed the efficacy of CBT interventions for the reduction of needle-related pain and distress in children. Very low and low-quality evidence supported the use of CBT for reducing behavioural distress (11 papers, 1105 participants, SMD -0.4). There was no evidence supporting the use of CBT for self-reported distress (6 papers, 234 participants, SMD -0.26) or observed-reported distress (6 papers, 765 participants, SMD -0.08). The authors concluded that nonetheless the potential benefits in reducing distress and/or pain for children supports the use of these techniques in clinical practice (Birnie *et al.*, 2018).

To date, the only Cochrane systematic review to examine the effectiveness of CBT for anxiety disorders in children and adolescents was published by James and colleagues in 2020. A total of 87 studies with 5964 participants were included in the review.

The review determined that there was insufficient available data to assess CBT vs alternative treatment on post-treatment remission of all anxiety disorders, but low-quality evidence suggests there may be no difference (OR 0.89, 95% CI 0.35 to 2.23; n = 401, four studies). This evidence is based on four studies. The authors concluded that CBT is probably more effective short term than waiting lists or no treatment and may be more effective than attention control. There was little to no evidence that CBT was superior to usual care or alternative treatments but confidence in these findings is limited due to concerns about the amount and quality of available evidence (James *et al.*, 2020).

A study focusing on intra-oral injection phobia treatment with CBT was published by Swedish researchers Berge and colleagues in 2016. They investigated the impact of immediate versus delayed treatment with CBT. Their chosen population were children aged ten to 16 years with identified intra-oral injection phobia in Western Norway (Berge *et al.*, 2016). A sample size calculation was completed with an effect size of 0.8, significance level of 0.05 and estimated attrition of 10%. This determined that at least 60 participants were required. The authors set a target sample size of 68, with 67 (39 girls and 28 boys) patients eventually recruited through convenience sampling who were eligible for randomisation. Of those 67, five discontinued treatments, leaving 62 assessments. A further four could not be followed up for the year period. The children were asked to complete four psychometric self-report instruments: the IOIF-s; the Children's Fear Survey Schedule-Dental Subscale (CFSS-DS); the Injection Phobia Scale for Children; Mutilation Questionnaire for Children. This was to record the fear scores in each different area for comparison. Patients were randomly assigned either immediate or delayed treatment with CBT. Participants were screened by trained clinical psychologists using a modified version of the Anxiety Disorders Interview Schedule which was delivered through a semi-structured interview. The interviews explored the children's maintaining factors. Children were asked to complete the self-report measures prior to entering the interview rooms.

The behavioural avoidance test (BAT) was administered by trained dentists and was standardised into 13 steps. The psychometric tests and BAT were repeated at each assessment, post treatment and at one-year follow up. Pre-treatment scores were not found to be significantly different between the immediate and delayed treatment groups. The immediate treatment group showed significantly decreased values in all four psychometric measures post treatment (IOIF-s (t(28) ¼ 12.8) CFSS-DS (t(29) ¼ 7.2), IS-c (t(29) ¼ 7.3) but the delayed treatment group did not. Similarly, the immediate treatment group also showed significant improvement in their ability to complete the BAT (t(28) ¼ 7.88, p < 0.001) while the delayed group did not.

The authors concluded that the most important finding was that CBT, performed by appropriately trained dentists, is effective and successful in the reduction of fear of dental procedures including intra-oral injection. They also commented on the successful use of the BAT in this paediatric population.

The effect of an intervention based on the principles of CBT for reducing pain and fear of children aged seven to 12 years old during intravenous (IV) insertions was assessed by Tuncay, Sarman and Budak (2023). The study, focusing on an intervention called 'SuperKid', took place in the outpatient department of a children's hospital in Eastern Turkey. A target sample size of 96 was determined through sample size calculation, with a set power of 95% and an alpha error of 5%. The authors recruited the required 96 children (48 girls and 48 boys) who were randomised to receive the CBT intervention or standard care. The intervention, SuperKid (SK), was comprised of six cards and six posters displayed on the walls. These demonstrate a story, with two characters (one boy and one girl) drawn to resemble children aged between four and eight years old. The characters have been hospitalised after falling unwell and need a blood sample. The story demonstrates the journey through hospital care, ending with the character being given a 'super elixir' through an IV. The story was developed in liaison with a paediatric psychotherapist, paediatric nurse, and psychologist. The intervention involved displaying the posters in the treatment room and showing the children the cards while telling them the story. Children, parents, and a researcher completed two outcome measures, the Children's Fear Scale (CFS) and the Wong Baker FACES pain scale. These were completed prior to randomisation, two minutes after and five minutes after the procedure. The authors reported that 41.7% of the SK group and 52.1% of the control group were most afraid of painful and invasive procedures in the hospital. Children's fear scores before the procedure were reported as statistically similar ($p > 0.05$).

Children in the control group were observed to have higher mean fear scores during and after the procedure (scores at T¹ T² T³: child - 1.31, 3.29, 1.65; mother - 1.42, 3.17, 1.29; researcher - 1.42, 3.40, 1.58) than the children in the SK group (scores at T¹ T² T³: child - 1.48, 2.65, 0.69; mother - 1.42, 3.12, 1.3; researcher - 1.42, 2.69, 0.67). The authors acknowledged some limitations to their study. The CFS is not designed for four-year-old children, but was used in the study with this cohort, which may have impacted the scores reported. The authors also mentioned that the inclusion of eight-year-olds may have affected their study schedule, and had some impact, although this was not further described. The clinical facility where the study was undertaken had a common area, where the crying of one child may have affected others, and therefore impacted their anxiety or fear.

The investigators also felt that the mother's report may not have been an accurate assessment of the child's feelings, and that some children may have purposely answered incorrectly to appear brave. They concluded that SK is an accessible and engaging means of reducing fear and pain from medical procedures among children.

Imamoglu and Ozdemir also investigated the use of a CBT based intervention for children aged seven to 12 undergoing venous access in their study, which took place in the paediatric clinic of a university hospital in Turkey (2024). They aimed to investigate the effect of a cognitive behavioural intervention (CBI) on the pain, fear and anxiety of children undergoing peripheral venous cannulation. The authors recruited and randomised 80 children to receive either the CBI or standard care. Three children were not followed up, leaving 77 children for data analysis (39 girls and 38 boys). The authors completed a post-hoc power analysis which determined that this sample would be sufficient to achieve 98% power and significance level of 0.05. The CBI in this study consisted of preparation and information, distraction, suggestions, caregiver training and positive reinforcement. Children were engaged with the researcher in social communication (distraction) and were given suggestions about the procedure (suggestion). The parent held the child's untreated hand. During the procedure, the researcher used a behavioural distraction method chosen in advance by the child (counting, singing, poems or talking).

After treatment was completed, the researcher provided the child with positive feedback such as 'you were very brave' alongside a sticker. Four outcome measures were used. Prior to the procedure, the child, parent, and researcher completed the Children's Fear Scale (CFS). After the procedure, the child was asked to complete the Visual Analog Scale (VAS) and Wong Baker FACES (WB FACES) scale to indicate pain levels, and the State-Trait Anxiety Inventory for children – state form (STAIC -State) and CFS to measure fear/anxiety. Once they had done so, the researcher and parent completed the VAS, WB FACES and CFS. The authors reported that no statistically significant difference was observed in the pre-procedural CFS mean scores between groups. They identified lower mean procedural STAIC-State scores in the CBI group (control 49.31, CBI 46.66. The effect sizes for the anxiety variables are reported to be moderate for both the CFS (self-report 1.37, caregiver-report 1.95, researcher-report 1.73) and STAIC-State (self-report 0.52). The authors acknowledged the following limitations of their work: it was not double-blinded due to the nature of the intervention, and the data were collected in an inpatient ward with no emergency instructions.

They concluded that the CBI group experienced less fear and anxiety than the control group, suggesting this method may be effective.

As this is the first study investigating this format of CBI, they suggested further exploration of how this method may be integrated into practice.

The limitations common to all studies were the participant populations, which were insufficient to generalise to a wider population and the inability to blind due to the inherent nature of the intervention.

In summary, CBT appears to be a potentially effective management for needle fear in children aged seven and above, addressing the associated unhelpful thoughts and feelings, however the evidence base for this is currently poor. Despite this, it continues to be recommended as a treatment for the management of specific fears including needle fear (Birnie *et al.*, 2018; James *et al.*, 2020).

2.3.3 Summary

The above literature review has clearly highlighted that child needle fear is an area of ongoing interest to clinical researchers, with reports of several novel techniques and interventions.

To date, topical anaesthetic application, CBT, and distraction are the only techniques which have been specifically investigated in the management of paediatric needle fear, but the literature base is limited. There is also a paucity of studies assessing the effectiveness of psychological therapies on the reduction of needle fear in childhood. As discussed in the introduction, there are also no formal clinical guidelines which recommend best treatment for needle fear (in adults or children), with clinicians relying on evidence of low quality and personal clinical experience.

There is evidence that a significant proportion of the population may be affected by a fear of needles, which can have major health implications. Despite this, there is a paucity of literature on the best management of childhood needle fear, with many studies focusing on adult patients.

At the time of writing, the literature on management of paediatric needle fear has mostly considered children in the younger age groups (up to 12 years old), with several studies being undertaken in Turkey specifically.

Although the literature base is increasing, the quality of the available evidence is open to some criticism.

Notably, studies appear to share the following methodological limitations:

1. Failing to ensure that children with needle fear are specifically included in the study, by failing to screen for this at any stage.
2. Poor rationale provided or considered for determining an adequate sample size to ensure the study is adequately powered.
3. A variety of measurement tools being used to measure needle fear, creating confusion and an inability to undertake comparative techniques such as meta-analysis. This results in the available evidence for specific techniques being poor despite a reasonable number of studies.
4. A lack of consideration of appropriate timepoints for measurement of primary outcome measures including
 - a. Use of a solo timepoint which cannot give any indication of change
 - b. Taking a second measurement *after* the procedure, when it could be assumed that anxiety will have naturally reduced
 - c. Failing to account for delays in changes to some physiological measures (such as a 30-minute delay between anxiety and associated rise in cortisol levels)
 - d. No long-term follow-up

Future research should aim to address these limitations through specifically seeking to include the target population in the study, ensuring a power calculation or similar rationale for sample size is undertaken and clearly described, aiming for a consensus on the most appropriate measure of paediatric needle fear to allow for consistency and careful consideration of the most appropriate timepoints to record these measurements.

Of the techniques that were described in use with children in this literature review, only one had evidence of development with young people and therefore many of these approaches may not meet their unique needs. New technologies are emerging which show early promise, most notably with electronic or virtual media, and the use of self-help techniques in the management of other medical fears. In the last two years, several novel interventions or tools have been developed (Xploro, Golden Breath, SuperKid as described above). The development of these tools and interventions is not always clearly described, so although they have been developed *for* young people with needle fear it is not clear if all have been developed *with* input from young people. Some tools have been developed for one or two specific procedures, such as blood tests (Xploro) and IV medications (Superkid). The early evidence suggests that these tools may be useful for young people with needle fear in appropriate situations.

Further research and innovation are required to develop and evidence a resource which will more definitively meet the needs of this population.

2.4 Measurement of needle fear

The measurement of needle fear, within the published literature, has been undertaken using several measures, single item ratings, and other methods which will be discussed in turn. Some measurement tools are specifically designed to assess needle fear, while others were developed for additional or more general anxiety but have been applied in studies on needle fear. Although the focus of this section will be on measures which have been used with children, some key adult measures are included for completeness.

2.4.1 Measurement tools for recording needle fear

For the purposes of this literature review, the measures are split into three broad categories:

1. a direct observation of the child's behaviour or physiological state in the context of an NBP
2. completion of a scale by a parent or observer as a proxy measure of anxiety
3. self – report scales completed by the child

The measures are summarised in table 2.1 below and discussed in more detail in the following sections.

	Measure	Advantages	Disadvantages
Direct observation of child's behaviour or physiological state	Behavioural Avoidance Test (BAT)	<ul style="list-style-type: none"> • can be used with a wide range of ages • can be used with a range of cognitive abilities and literacy skills • assesses avoidance 	<ul style="list-style-type: none"> • not assessed for use with children with needle fear • cannot assess anxiety related to specific steps or hypothetical • does not assess anxiety directly
	Proxy observation	<ul style="list-style-type: none"> • validated with children • easy to use • does not rely on literacy 	<ul style="list-style-type: none"> • not as reliable as self-report measures • parents and proxy observers likely to over or underestimate • cannot assess physiological symptoms or thoughts about needle fear
	Physiological measurement (such as heart rate or cortisol levels)	<ul style="list-style-type: none"> • objective measurement • measurement of heart rate or salivary cortisol is simple and painless • can be used with any age of child • can detect distress 	<ul style="list-style-type: none"> • requires specialist expertise for collection and storage • requires specialist equipment for collection of data and/or analysis • timing is critical • difficult to establish accurate baseline • cannot detect cause of distress
Proxy Reporting Tools	Visual Analog Scale (VAS)	<ul style="list-style-type: none"> • validated with children in other settings • adaptable to any question • defined minimally important difference • can be used as a self-report measure with children 	<ul style="list-style-type: none"> • not developed with children • was not specifically designed for measuring needle fear • cannot record physical symptoms or thoughts about fear

Self-Reporting Tools	Children's Fear Scale (CFS)	<ul style="list-style-type: none"> specifically developed for measuring needle fear in children (5-10 years) can be adapted to any question validated with children 	<ul style="list-style-type: none"> not developed with children not validated with children over ten or under five cannot record physical symptoms or thoughts about fear no defined minimally important difference
	Intra-oral Injection Fear Scale (IOIF-s)	<ul style="list-style-type: none"> specifically developed to measure fear of intra-oral injections in children (10-16years) validated with children clearly defined definition of high anxiety 	<ul style="list-style-type: none"> not developed with children not validated with children under ten measures only fear of intra-oral injections cannot record physical symptoms no defined minimally important difference only available and validated in the original Norwegian
	APA DSM5 Severity Measure for Specific Phobia	<ul style="list-style-type: none"> developed to assess the severity of specific phobias in children (11-17 years) 	<ul style="list-style-type: none"> unvalidated no defined minimally important difference cannot measure physical symptoms not developed with children
	Injection Phobia Scale – Anxiety (IPS-Anx)	<ul style="list-style-type: none"> specifically designed to measure general needle fear validated with children an adaptation for children has been developed 	<ul style="list-style-type: none"> very long the adaptation for children was not developed with children, and has not been validated thoroughly cannot record physical symptoms no defined minimally important difference
	Self Injection Assessment	<ul style="list-style-type: none"> developed to measure anxiety related to self-injection short and easy to use 	<ul style="list-style-type: none"> not developed with or for children not validated with children cannot measure physical symptoms

Questionnaire (SIAQ)		<ul style="list-style-type: none"> measures only fear of self-injection
Modified Child Dental Anxiety Scale	<ul style="list-style-type: none"> adapted for use with children validated with children (aged five to 12 years) faces or numerical scale can be used contain one item on needles (in the back of the hand) defined level of fear related to score 	<ul style="list-style-type: none"> developed for measurement of dental anxiety contain only single item related to needles cannot measure general needle fear cannot measure physical symptoms
Child Anxiety Measure (CAM)	<ul style="list-style-type: none"> developed for measurement of anxiety in children can be adapted to any question 	<ul style="list-style-type: none"> not developed with children not developed for measurement of needle fear specifically insufficient evidence of validity and reliability cannot measure physical symptoms no defined minimally important difference
Venham Situational Anxiety Score	<ul style="list-style-type: none"> developed with children developed to measure anxiety in children can be used with wide range of ages 	<ul style="list-style-type: none"> developed for measurement of dental anxiety not revalidated in contemporary population image is clearly a white male child and may not be representative or inclusive

Table 2.1 Summary of tools for measurement of needle fear

Direct observation of the child's behaviour or physiological state

Behavioural Avoidance Tests

Behavioural Avoidance Tests (BATs) are defined by the American Psychological Association as 'an assessment technique that observes an individual approach a feared situation until he or she is unable to go further'. The BAT is used to assess levels of avoidance and fear of specific situations associated with phobias. Variables that can be measured using the BAT include physical symptoms (e.g., increased heart rate), escape or avoidance strategies, and subjective ratings of fear. The test requires tailoring to the specific fear held by the individual. This tool can be applied clinically in the form of graded exposure, such as the needle desensitisation technique described by Taylor and Campbell in 2015. This type of measurement tool may be difficult to use in some studies related to needle fear, as the child cannot ethically be exposed to an NBP that they do not need. Berge and colleagues utilised a BAT for intra-oral injections alongside their Intra Oral Injections Fear Scale in their 2017 paper, described above. One further study protocol by Wright and colleagues was identified which has proposed using this test to assess the impact of one session versus multi-session CBT in the management of various phobias, including needle phobia, in children (Wright *et al.*, 2018). The properties of the BAT for needle or injection fear have not been evaluated in the published literature.

BATs can be used with children from a wide range of ages, literacy skills and cognitive abilities and would allow for assessment of avoidance in the participant. It cannot assess for levels of anxiety related to specific steps or hypothetical scenarios and does not assess thoughts. There is no evidence in the literature of its validity or reliability for use with children in this setting. It is not routinely used through the literature on needle fear in children, suggesting there may be barriers to its use in practice.

Proxy observation

Proxy observation refers to the determination of distress or anxiety of the child being completed by a third-party. This third-party could be the parent or carer, a healthcare worker or researcher. A commonly used observational scale is the Observation Scale of Behavioural Distress (OSBA) first described by Elliot, Jay and Woody (1987).

It was designed as an 11-item revision of an earlier scale, the Procedure Behaviour Check List, with the hypothesis that the revised scale would be a more sensitive and valid measure than its predecessor. The OSBA is designed to be completed every 15 seconds, and the contents are weighted according to severity.

An initial study with a small sample revealed little to any improvement in sensitivity and validity, and therefore the developing authors completed a further validation study in 1986 with a larger sample size to replicate and expand on the original, with the focus on younger children. A consecutive sample of 55 children (20 girls and 35 boys) with leukaemia were recruited to the study. Children were aged between three-13 years, with 70% younger than eight years old. The children were all part of a separate longitudinal study evaluating the impact of pre-procedural conditions on distress during bone marrow aspiration treatment. The children were asked to watch a 30-minute cartoon prior to having treatment. An observer watched children undergo their bone marrow aspiration and recorded scores on the OSBA at 15 second intervals, which were indicated through an audiotape and headphones. The observers had been trained by the second author for six to eight weeks in the use of the tool. The training was complete when the observer was able to reach a score of 75% reliability over six consecutive procedures.

Children were also asked to rate 'how scared' they felt before the procedure using a basic faces scale and had their heart and blood pressure taken on arrival to the clinic before the procedure and three to five minutes after completion of the procedure. A nurse who assisted the clinician in completing the procedure was asked to rate the degree of distress exhibited by the patient using a five-point Likert scale. A Pearson's analysis was completed for two observers with a score of $r = 0.98$. The mean agreement score was 84%. Correlation coefficients between the OSBD and other measures showed statistically significant correlation between the OSBD and the nurse rating ($r=0.69$), self-reported fear ($r=.38$), heart rate ($r=.38$) and blood pressure ($r=.32$) at $p<0.001$. The authors concluded that the evidence supported the validity and reliability of the measure.

Some studies assessing childhood fear have relied solely on a proxy observation to attribute levels of distress, including three which focus on fear of needles (Ouach *et al.*, 2019; Vagnoli *et al.*, 2015; Dahlquist *et al.*, 2002). A review of the literature revealed three studies: one cross-sectional study and two interventional trials. These studies used a proxy observation for children aged from six-months to 18-years. Two studies were undertaken in North America (Ouach *et al.*, 2019; Dahlquist *et al.*, 2002) and one in Italy (Vagnoli *et al.*, 2015). Studies were set in secondary healthcare settings, in vaccination clinics (Ouach *et al.*, 2019) and hospital wards (Vagnoli *et al.*, 2015; Dahlquist *et al.*, 2002).

Participant numbers ranged from six – 283. There was variance in the timing of the use of the observation between studies, with some studies measuring a static time point and others additionally using the observation to assess for changes in levels of fear. The exact tool used for the proxy assessment also varied between studies.

Proxy observations have the advantage of being easy to use and apply and obviate the need for measures to be developed with children or employ child appropriate language. Research by Engel, Rodrigue and Gefken in 1994 and Klein in 1991 suggests however that child self-reported measures are more accurate and reliable for psychological functions. It was also shown that parents and carers are likely to over or under-estimate the amount of distress encountered by children during medical procedures. It would therefore be inappropriate to consider proxy observations when self-report methods exist for use in childhood.

Physiological measurement

Physiological measurement of anxiety can include monitoring of respiratory rates, heart rate, blood cortisol levels and oxygen saturation which would be expected to rise in cases where a person is experiencing higher levels of stress or anxiety. Use of such measurements requires appropriate monitoring equipment and expertise in analysing this biophysiological data. Salivary assessment, another form of physiological measurement, refers to an analysis of saliva with the aim of measuring or quantifying anxiety levels. It is suggested that salivary measurements are an attractive alternative to blood sampling for research trials as the blood sampling itself can cause raised anxiety and may be difficult to obtain in some populations (Hellhammer, Wüst, and Kudielka., 2009).

A review of the literature revealed that the use of physiological measurement of needle fear in children is limited. Two studies were identified: two randomised controlled trials (Küçük and Yaman Aktaş., 2019; Nilsson *et al.*, 2015). The studies included children aged five to 12 years old. One study was undertaken in Turkey and the other in Sweden. The studies were undertaken in schools and a secondary care setting. Participant numbers were 40 and 210 respectively. Salivary cortisol was the measure chosen in both studies, taken before the procedure and again 30 minutes later. The Turkish study also required participants to self-report anxiety at a single time-point on the Children's Fear Scale (CFS - Küçük and Yaman Aktaş., 2019). Both sets of authors showed awareness of the 30-minute delay in changes to cortisol levels. Neither team reflected on the limitations of their measurement tool/s.

Cortisol is a steroid hormone which helps the body respond to increased stress and has been suggested to be an effective measure of stress through salivary testing (Tammayan, Jantaratnotai, and Pachinsawat., 2021). The benefit of using a salivary testing measure is that it is an objective measurement and can be used in any age of child. It is simple and painless to collect and should not elicit any distress. The disadvantage is the requirement for special equipment to collect and store the samples, and a lab able to process the samples. Salivary cortisol levels rise approximately 30 minutes after exposure to a stimulus, and therefore timing is critical. It can also be difficult to obtain a true baseline reading, as children may have begun to feel anxious or stressed prior to attending their appointment. It also cannot detect the cause of the distress.

Proxy completion of scales

The Visual Analog Scale

The Visual Analog Scale (VAS) is a single item question which attempts to measure an attitude or characteristic over a continuum of values. An example, shown in figure 2.1 would be to measure the amount of pain felt by a person, suggested by Gould and colleagues, where this could range from 'no pain' to the 'worst pain possible' (Gould *et al.*, 2001).

How severe is your pain today? Place a vertical mark on the line below to indicate how bad you feel your pain is today.

No pain | _____ | Very severe pain

Figure 2.1 a Visual Analog Scale used to measure pain severity (Gould *et al.*, 2001)

The VAS is normally represented on a horizontal line of 100mm in length, with descriptors at each end. The person marks the point along this line where they feel their pain is at that moment. Its original creation has been widely accepted as attributable to Hayes and Patterson in 1921 initially as a proxy scale for supervisors to grade their satisfaction with their workers, before being adapted as a tool for use in healthcare. Some specialties have developed a VAS specific to their service or procedure – such as anaesthetists and gastroenterologists. Its use as a proxy scale continues, although it is also used for self-reporting.

A study by Williams and colleagues looked to assess the responsiveness of the VAS for measuring changes in level of general anxiety. The study included 22 adult patients with general anxiety disorder aged 21-59. The patients completed a VAS scale daily, alongside two other validated measures for their condition. This study concluded that a preliminary minimally important difference would be between ten and 15mm (Williams *et al.*, 2010).

A VAS designed to measure general anxiety has also been validated for use with children. Bernstein and Garfinkel investigated the validity of a VAS for anxiety, the Visual Analogue Scale for Anxiety – Revised (VAA-R) in school refusers in a sample of 1004 children aged between 8.6 and 17.6 years of age. 11 items were included:

- 1) Being called on by the teacher
- 2) Getting short of breath; heart racing or pounding and dizziness
- 3) Starting school in the fall
- 4) Eating alone in the lunchroom
- 5) Going away to summer camp
- 6) Riding the school bus
- 7) How I feel most of the time
- 8) Thinking about going to school on Monday AM
- 9) Standing up and speaking in front of class
- 10) Walking into the school building
- 11) How I feel right now

The children were asked to score the VAA-R along a scale from 'jittery/nervous' to 'steady' (Bernstein and Garfinkel., 1992). The authors used a convenience sample of 86 school refusers (36 girls and 50 boys) and a sample of 918 attenders (gender breakdown not stated) in grades nine to 12 from the local public high school in Minnesota, Midwestern America. The VAS was compared to two already validated anxiety measures – the State-Trait Anxiety Inventory for Children (STAIC) and the Revised Children's Manifest Anxiety Scale (RCMAS). The sample of school refusers had their notes blind reviewed by the author and a senior psychiatry resident to screen for any anxiety or depressive disorders. In the school sample, the internal reliability was reported as a coefficient alpha (Cronbach's alpha) of 0.74 for males, 0.81 for females, and 0.80 overall. This suggests a good level of internal reliability. Test – retest validity was assessed using only 16 of the participants. This resulted in a correlation coefficient of 0.87, which would suggest the retest validity is reasonably strong however this is a very small sample, and therefore cannot be confidently asserted. The validity of the VAS was also assessed through comparison to the two previously validated measures, the STAIC and the RCMAS.

The Pearson's correlations were 0.63 and 0.61 respectively, suggesting a moderately positive relationship. In the community sample of 918 children from the local public high school, the internal reliability was reported as a coefficient alpha of 0.79 for males, 0.77 for females and 0.78 overall. This suggests an acceptable level of internal reliability. Overall, this study makes a good argument for the internal validity of a VAS as an anxiety measurement tool but fails to convince regarding test-retest validity. No further studies investigating the validity of an English language VAS for the purpose of measuring anxiety in children were found.

Despite not being specifically designed for anxiety, a VAS self-report methodology has been used in several studies investigating needle fear in a paediatric population (Wong, Lui and Choi., 2023; Gold *et al.*, 2021; Takemura *et al.*, 2021; Dunn *et al.*, 2019; Piskorz and Czub., 2018; Hedén, von Essen, and Ljungman., 2016; Hedén, von Essen, and Ljungman., 2014; Brenner *et al.*, 2013; von Essen and Ljungman., 2011; Dufresne *et al.*, 2010; Hedén *et al.*, 2009; Hedén, von Essen, and Ljungman., 2009). It is particularly popular with the Swedish researcher Hedén, as evidenced by its use in multiple studies.

The studies cited above were pilot or full RCTs, cross-over RCTs, non-randomised trials and quasi-experimental trials. The reviewed studies used a VAS with children aged from one upwards, with children asked to self-report from the age of seven-years. Five studies were undertaken in Sweden (Hedén, von Essen, and Ljungman., 2016; Hedén, von Essen, and Ljungman., 2014; von Essen and Ljungman., 2011; Hedén *et al.*, 2009; Hedén, von Essen, and Ljungman, 2009), four studies were undertaken in North America (Gold *et al.*, 2021, Dunn *et al.*, 2019, Brenner *et al.*, 2013, Dufresne *et al.*, 2010), one study was undertaken in Poland (Piskorz and Czub., 2018), one study was undertaken in Japan (Takemura *et al.*, 2021) and a further, more recent study, was undertaken in Hong Kong (Wong, Lui and Choi., 2023).

Studies appear to be mainly set in secondary healthcare settings, including hospital wards (Wong, Lui and Choi., 2023; Gold *et al.*, 2021; Dunn *et al.*, 2019; Piskorz and Czub., 2018; Hedén, von Essen, and Ljungman., 2016; Hedén, von Essen, and Ljungman, 2014; Brenner *et al.*, 2013; von Essen and Ljungman., 2011; Dufresne *et al.*, 2010; Hedén *et al.*, 2009; Hedén, von Essen, and Ljungman., 2009) and dental hospitals (Takemura *et al.*, 2021). Participant numbers have ranged widely from 14 – 1500. There is also great variance in the number of scores recorded and timing of the use of the VAS between studies, with some studies measuring a static time point and others additionally using VAS to assess for changes in levels of fear.

Three studies relied solely on self-reported scores, two studies recorded self-reported scores for children over the age of seven alongside proxy reports and the remaining study relying on proxy reporting. One study specifically mentions and utilises a minimally important difference of 15mm (as evidenced for pain) to draw conclusions.

Wong, Lui and Choi (2023) used a VAS to assess anxiety in their study, investigating the effectiveness of immersive virtual reality when compared to standard care in children undergoing venepuncture. The primary aim of the study was to assess the impact on pain, anxiety, stress, and procedure length. Secondary aims were to assess healthcare provider satisfaction, and cost-effectiveness. The study was conducted with 149 children aged four to 12 years in the paediatric unit of a public hospital in Hong Kong. Anxiety was measured as a secondary outcome using a VAS, the short version of the Chinese state anxiety scale and physiological measures (heart rate and salivary cortisol). The VAS was self-reported, and data collected ten minutes before, immediately after and 30 minutes after the procedure. There are no discussions regarding limitations of using a VAS in these published papers, and the question which accompanied the scale is never reported.

In summary, the VAS has many advantages as a single item measure. It can be adapted to suit the clinical or research question, and researchers appear to have confidence in its use for measuring presence and changes in degree of needle fear. The primary validation study suggests the scale generally may have good reliability and validity. However, it has not been designed specifically for assessing anxiety related to needle fear and it has not been validated as a tool for the measurement of change in levels of needle fear. It is not able to record physiological symptoms or thoughts about fear. There is however a generally accepted minimally important difference of 15 mm (on a 100 mm scale), meaning it could be used to assess the effectiveness of an intervention in the reduction of needle fear.

Self- report scales

Children's Fear Scale

The Children's Fear Scale (CFS) is a self-report single item fear measure, based on the adult Faces Anxiety Scale (McKinley, Coote, and Stein-Parbury., 2003), developed for use in a paediatric population by McMurtry *et al.*, in 2011 specifically for recording fear related to NBPs. The scale is comprised of five sex-neutral faces, scored 0 - 4, commencing with a neutral expression which gradually becomes more concerned (figure 2.2).

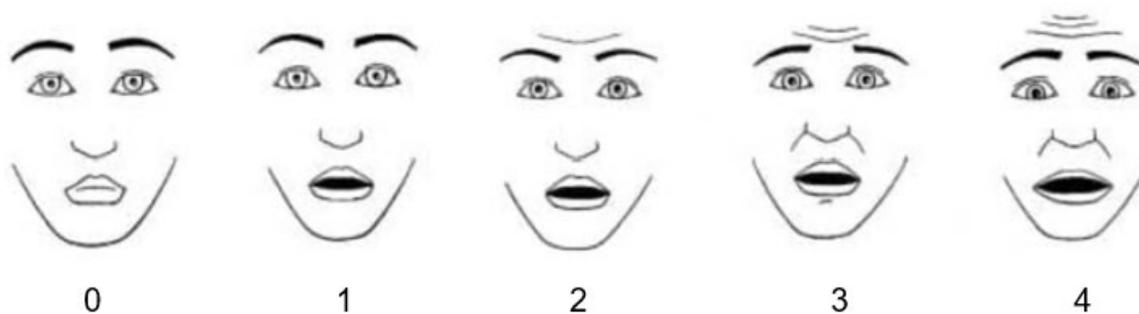


Figure 2.2 the Children's Fear Scale with added numerical identifiers (McMurtry *et al.*, 2011)

The child is asked to choose the face that best represents their feelings at that moment in time. However, there is no defined score for assessing severity of anxiety (McMurtry *et al.*, 2011). The tool is designed to be used with any form of NBP.

It was investigated for preliminary validity by McMurtry and colleagues in 2011. A convenience sample of 100 children aged between five and ten years-old was taken from a hospital outpatient venepuncture clinic in Canada (McMurtry *et al.*, 2011). The CFS was compared with an already validated measure – the Children's Anxiety and Pain Scale (CAPS). The convergent validity between the measures was demonstrated as 0.73 at initial record, and 0.83 when retested two weeks following the procedure. This suggests good validity compared to the CAPS measure. The test-retest validity was undertaken with all participants repeating the measure, two weeks following their venepuncture. The correlation coefficient was reported as 0.76 suggesting a reasonably strong validity. The authors did not investigate the reliability of the CFS, based on the premise first suggested by Beyer and Knapp in 1986 that if researchers can demonstrate high validity, reliability is assumed. The authors concluded that there was good evidence for the validity, and therefore reliability, of the measure but stated that this was a preliminary investigation and assessment only, and that further research should be undertaken. To date, no further studies have further investigated or confirmed the psychometric properties of the CFS in English. Furthermore, there are no defined minimally or clinically important difference in scores that can be correlated with the child's reaction to a needle exposure.

The CFS was validated for use in a Turkish population by Gerçeker and colleagues in 2018 alongside the Child Anxiety Meter (CAM - described later in this section). The resulting paper was published in Turkish, with the English abstract stating that the study was completed with 135 children aged four to ten-years in the paediatric services of a university hospital in Turkey.

The authors reported a content validity index of 0.89 for the CFS, a correlation coefficient of 0.99 between the CFS and CAM scales, and negative correlations between the fear scores and child age. There was reported to be a positive relationship between CFS score and a history of chronic illness. The authors asserted that the CFS is a valid and reliable tool, appropriate for use in the Turkish paediatric population (Gerçeker *et al.*, 2018).

To date, the CFS has been used with relative frequency in clinical trials investigating needle fear in a paediatric population. Some of these studies are discussed below (Aydos *et al.*, 2024; Çelik and Düzkaaya., 2024; Düzkaaya *et al.*, 2024; Gerçeker, Bektaş, and Yardımcı., 2024; Imamoglu and Ozdemir., 2024; Kırbaş and Kahrıman., 2024; Oluc and Fatma., 2024; Savaş, Semerci, and Bayram., 2024; Suleman *et al.*, 2024; Abdullah and Suat., 2023; Semerci, Akarsu and Kiliç 2023; Tuncay, Sarman and Budak., 2023; Erdogan and Aytekin., 2021; Gerçeker *et al.*, 2021; Kurudirek, Arikan, and Sarialioğlu., 2021; Arikan and Esenay., 2020; Caruso *et al.*, 2020; Düzkaaya *et al.*, 2020; Gerçeker *et al.*, 2020; İnangil, Şendir, and Büyükyılmaz., 2020; Osmanlliu *et al.*, 2020;; Özkan and Polat, 2020; Chen *et al.*, 2019; Inan and Inal., 2019; Küçük and Yaman., 2019; Chad, Emaan, and Jillian., 2018; Jibb *et al.*, 2018; Stoltz and Manworren., 2017; Dalley and McMurtry., 2016; ; Canbulat, İnal, and Sevim., 2015; Canbulat, Inal, and Sönmezer., 2014).

All the 31 reviewed studies used the CFS as a self-report measure with children, aged from between four to 18 years, except the Suleman study which used the scale with parents only. The geographical spread of the included studies are shown in table 2.2 below.

Country	No of studies	References
Turkey	23	<p>Aydos <i>et al.</i>, 2024 Çelik and Düzkaaya 2024 Düzkaaya <i>et al.</i>, 2024 Gerçeker, Bektaş, and Yardımcı., 2024 Imamoglu and Ozdemir., 2024 Kırbaş and Kahrıman., 2024 Oluc and Fatma., 2024 Savaş, Semerci, and Bayram., 2024 Suleman <i>et al.</i>, 2024 Abdullah and Suat., 2023 Semerci, Akarsu and Kiliç 2023 Tuncay, Sarman and Budak., 2023 Erdogan and Aytekin., 2021</p>

		Gerçeker <i>et al.</i> , 2021 Kurudirek, Arikan, and Sarialioğlu., 2021 Arikan and Esenay., 2020 Düz kaya <i>et al.</i> , 2020 Gerçeker <i>et al.</i> , 2020 İnangil, Şendir, and Büyükyılmaz., 2020 Özkan and Polat., 2020 Inan and Inal., 2019 Canbulat, İnal, and Sevim., 2015 Canbulat, Inal, and Sönmezer., 2014
North America	6	Caruso <i>et al.</i> , 2020 Osmanlliu <i>et al.</i> , 2020 Chad, Emaan, and Jillian., 2018 Jibb <i>et al.</i> , 2018 Stoltz and Manworren., 2017 Dalley and McMurtry., 2016
Taiwan	1	Chen <i>et al.</i> , 2019
Iraq	1	Suleman <i>et al.</i> , 2023

Table 2.2 Geographical spread of studies using Childrens Fear Scale

The majority of studies (23) have been undertaken in Turkey where there appears to be some consistency in its use. The measure has not been evaluated or used in any studies in the United Kingdom to date.

Studies appear to have been mainly set in secondary care hospital settings. The study locations are summarised in table 2.3 below.

Setting	References
Hospital wards	Savaş, Semerci, and Bayram., 2024 Düzkaya <i>et al.</i> , 2024 Imamoglu and Ozdemir., 2024 Semerci, Akarsu and Kiliç 2023 Tuncay, Sarman and Budak., 2023 Gerçeker <i>et al.</i> , 2021 Arikan and Esenay., 2020 Caruso <i>et al.</i> , 2020 Düzkaya <i>et al.</i> , 2020 Osmanlliu <i>et al.</i> , 2020 Chen <i>et al.</i> , 2019 Jibb <i>et al.</i> , 2018 Stoltz and Manworren., 2017
Phlebotomy services	Aydos <i>et al.</i> ,2024 Çelik and Düzkaya., 2024 Gerçeker, Bektaş, and Yardımcı., 2024 Oluc and Fatma., 2024 Suleman <i>et al.</i> ,2024 Abdullah and Suat., 2023 Erdogan and Aytekin., 2021 Kurudirek, Arikan, and Sarialioğlu., 2021 Gerçeker <i>et al.</i> , 2020 Özkan and Polat., 2020 Inan and Inal., 2019 İnangil, Şendir, and Büyükyılmaz., 2017 Canbulat, Inal, and Sönmezer., 2014
Vaccination clinics	Chad, Emaan, and Jillian., 2018
Veterinary surgery	Dalley and McMurtry., 2016
Schools	Kırbaş and Kahrıman., 2024 Canbulat, İnal, and Sevim., 2015.

Table 2.3 Settings of studies using Children’s Fear Scale haha

Participant numbers ranged widely from 11 – 477. Most studies used the CFS to measure change in levels of needle fear after an intervention. Some studies (11) relied on self-reporting, 19 studies relied on a combination of self and proxy reporting and one used proxy reporting only. Two teams of authors reported the question which accompanied the CFS.

Dalley and McMurtry asked “*Imagine a doctor using this needle to give you some medicine. What I would like you to think about quietly in your head is how scared you would feel if a doctor put this needle in your arm.*” (Dalley and McMurtry., 2016). Küçük and Yaman asked “*Can you look at these faces and choose the one which shows how frightened you are of having a phlebotomy*” (Küçük and Yaman., 2019). The remaining studies did not report the question within their published work. None of the research teams reflect on the limitation of the CFS, or on the use of proxy scores where these were obtained. There is no reference to responsiveness to change.

The CFS has many advantages as a single item measure. It can be adapted to suit the clinical or research question, it has been specifically designed for use with children aged five to ten-years, and researchers appear to have confidence in its use for measuring presence and changes in degree of needle fear. The primary validation study suggests the scale has good reliability and validity and it has been validated for use in a non-Western population (Turkey). However, it cannot be used to assess any physical reactions, thoughts or behaviour which are related to or support needle fear.

The CFS while developed *for* children has no evidence of having been designed specifically with children in the paper in which it was presented. It has not been specifically validated for responsiveness to change in levels of needle fear and therefore there is no defined or generally accepted minimally important difference. Within the published literature, there seems to be a tendency to use the measure for proxy reporting by parents or observers despite its development as a self-report tool and the limitations of proxy reporting.

Intra-Oral Injection Fear Scale

The Intra-Oral Injection Fear Scale (IOIF-s) is a 12-item questionnaire, developed for use in a paediatric population and specifically for measuring children’s fear of intra-oral injections (Berge *et al.*, 2016). The Norwegian developers found that previous measures failed to differentiate between intra- and extra-oral injections, or simply included the fear of dental injections as a single item within a broader scale. They therefore felt that a new measure was warranted. The IOIF-s is comprised of 12 scenarios in Norwegian, which have a score of one to five (figure 2.3).

The child is asked to self- score how they feel about each situation, with one being least anxious and five being the most anxious.

- IOIF-s 1: when the dentist tells you that you will need an anaesthetic injection
- IOIF-s 2: when you feel the sting from the syringe
- IOIF-s 3: when the dentist applies anesthetic ointment to your gums
- IOIF-s 4: for the anesthetic liquid itself
- IOIF-s 5: when you see a picture of a person being anesthetized at the dentist
- IOIF-s 6: when someone tells you that they have had an anesthetic injection at the dentist
- IOIF-s 7: that the sting from the syringe will be painful
- IOIF-s 8: when you are sitting in the dentist's chair preparing to have an anesthetic injection
- IOIF-s 9: when you can feel the anesthetic starting to work (numbness)
- IOIF-s 10: that the anesthetic will not work
- IOIF-s 11: when you see the needle of a syringe
- IOIF-s 12: when you see a picture of a dentist's syringe

Figure 2.3 the Intra-Oral Injection Fear Scale direct English translation (Berge *et al.*, 2016)

The IOIF-s was preliminarily evaluated for use by Berge and colleagues. The study looked at two samples of ten to 16-year-old children: 1460 elementary school pupils and 67 children who had been referred to a centre for dental phobia and who had a diagnosis of fear of intra-oral injections (Berge *et al.*, 2016). The internal reliability of the IOIF-s is reported at 0.95 which demonstrates excellent reliability. The validity is reported as 0.78 when compared to the child's self-rating of their anxiety, which suggests good construct validity. A sample of 26 random participants were asked to repeat the measure five weeks later, with a test-retest reliability of 0.79 which suggests good reliability. The test-retest reliability is based on a very small sample, and the measure is only currently formally available and evaluated in the original Norwegian, although the questions were translated for the publication of their paper into English. The receiver-operating characteristic curve indicated that a cut off score of 38 would be appropriate to detect IOI fear with a sensitivity of 0.61 and a specificity of 0.85. If the cut off was reduced, the sensitivity increased but the specificity decreased. To date, no further studies have further investigated or confirmed the psychometric properties of the IOIF-s although it has been used in two further studies by the developing author (Berge *et al.*, 2017; Berge *et al.*, 2016). It is not presently been translated or validated for use in any other languages.

A review of the literature revealed that the use of physiological measurement of needle fear in children is limited to two further studies by the developing authors (Berge *et al.*, 2016 and Berge *et al.*, 2017). One study was a cross-sectional design and the other a randomised controlled trial. The studies both included children aged ten-16 years old. The earlier study was set in schools with the second study undertaken in a secondary dental care setting. Participant numbers were 1441 and 62 respectively. The school study measured static fear and the secondary care study assessed for change in needle fear. There is no reference to responsiveness of the tool for measuring change. The authors did not discuss any limitation of the tool within the studies.

The IOIF-s is a novel scale, which has great potential for use in studies related to intra-oral injection fear. Preliminary work suggests this scale has good reliability and validity, and it has a clearly defined cut off for high levels of anxiety. The test-retest validity however was based on a very small sample, so this may not be entirely accurate. The scale evaluates feelings related to several specific dental scenarios. It does not assess for any physiological symptoms or thoughts associated with the scenarios. It has been designed for use in ten–16-year-olds which is a restrictive range. Although the measure was developed *for* use with children, there is no evidence in the published development paper that children were involved in its development.

Unfortunately, this measure is not available in any additional languages at present, meaning it has not been evaluated in other populations (other than Norwegian), and it is entirely specific to dental intra-oral injections, meaning the scenarios cannot be applied to any other form of NBP.

APA DSM5 Severity Measure for Specific Phobia

Craske and colleagues developed the American Psychological Association (APA) DSM5 Severity Measure for Specific Phobia in 2013. It is a ten-item questionnaire designed to assess the severity of specific phobias in children aged 11- to 17-years although the properties of the measure have not been evaluated. It is available for clinicians and researchers to download free of charge on the developers' website. The measure asks the child participant to first select their fear from five pre-decided options: driving, flying, tunnels, bridges, or enclosed spaces; animals or insects; heights, storms or water; blood, needles or injections; choking or vomiting. The child then responds to the ten items, marking how often they have experienced each category within the last seven days. Each answer has a corresponding score: 'never' is zero, 'occasionally' is one, 'half the time' is two, 'most of the time' is three and 'all of the time' is four (figure 2.4).

Severity Measure for Specific Phobia—Child Age 11–17

Name: _____ Age: _____ Sex: Male Female Date: _____

The following questions ask about thoughts, feelings, and behaviors that you may have had in a variety of situations. Please check (✓) the item below that makes you most anxious. Choose only one item and make your ratings based on the situations included in that item.						
<input type="checkbox"/> Driving, flying, tunnels, bridges, or enclosed spaces	<input type="checkbox"/> Animals or insects	<input type="checkbox"/> Heights, storms, or water	<input type="checkbox"/> Blood, needles, or injections	<input type="checkbox"/> Choking or vomiting		
Please respond to each item by marking (✓ or x) one box per row.						Clinician Use
During the PAST 7 DAYS, I have...	Never	Occasionally	Half of the time	Most of the time	All of the time	Item score
1. felt moments of sudden terror, fear, or fright in these situations	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	
2. felt anxious, worried, or nervous about these situations	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	
3. had thoughts of being injured, overcome with fear, or other bad things happening in these situations	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	
4. felt a racing heart, sweaty, trouble breathing, faint, or shaky in these situations	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	
5. felt tense muscles, felt on edge or restless, or had trouble relaxing in these situations	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	
6. avoided, or did not approach or enter, these situations	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	
7. moved away from these situations or left them early	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	
8. spent a lot of time preparing for, or procrastinating about (i.e., putting off), these situations	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	
9. distracted myself to avoid thinking about these situations	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	
10. needed help to cope with these situations (e.g., alcohol or medications, superstitious objects, other people)	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	
Total/Partial Raw Score:						
Prorated Total Raw Score: (if 1-2 items left unanswered)						
Average Total Score:						

Craske M, Wittchen U, Bogels S, Stein M, Andrews G, Lebeu R. Copyright © 2013 American Psychiatric Association. All rights reserved. This material can be reproduced without permission by researchers and by clinicians for use with their patients.

Figure 2.4 the APA DSM5 Severity Measure for Specific Phobia (Craske et al., 2013)

The items are individually scored, and a cumulative total recorded. There is no defined scale provided to define mild, moderate, or severe levels of fear. It is not described how this tool was developed. The properties of the tool have not been evaluated and it has not been used in any published studies to date.

Injection Phobia Scale - Anxiety

The Injection Phobia Scale – Anxiety (IPS-Anx) is an 18-item measure, specifically designed to assess anxiety relating to injections and associated medical experiences in an adult population by Öst and colleagues (figure 2.5). Each item is rated according to a five-point Likert scale, depending on how anxious the person feels about it. The scale for each question ranges from zero (indicating no anxiety) to four (maximum anxiety), with a maximum total score of 72. There is no defined score for assessing severity of anxiety. The clinically significant change is defined by the original authors as a reduction of 15 between total scores in an individual (Öst et al., 1992).

IPS-Anx item

10. Listening to someone talking about injections
 12. Watching a film about a person getting a shot
 9. Looking at a picture of a person getting a shot
 11. Looking at and touching veins in the crook of the arm
 3. Looking at a picture with a syringe and needle
 14. Watching a person in a nurse uniform
 4. Sensing the smell of a hospital
 18. Watching another person having a finger pricked in reality
 13. Watching another person getting a shot in reality
 7. Watching another person having a venipuncture in reality
 2. Having a shot in the upper arm
 17. Getting an intravenous injection
 6. Having a venipuncture (needle inserted into vein)
 16. Getting a vaccination
 5. Having an anesthetic injection at the dentist's
 15. Having one's ears pierced
 8. Getting an injection in the buttock
 1. Giving a blood sample by having a finger pricked
-

Figure 2.5 the Injection Phobia Scale – Anxiety (Öst *et al.*, 1992)

There is a shorter version of the IPS-Anx, the Injection Phobia Scale Anxiety Short Form (IPS-SF), which was developed for brevity by Olatunji and colleagues in 2010 and excludes the additional situational items (figure 2.6). It is also graded on the same five-point Likert Scale but has only eight items giving a total maximum score of 32 (Olatunji *et al.*, 2010).

IPS-SF

Below follows a description of a number of situations in which persons with injection phobia can experience anxiety or fear. Read each item and rate on a scale from 0 to 4 how much anxiety you would experience if you actually were in the situation.

	No			Max	
	Anxiety			<u>Anxiety</u>	
1. Giving a blood sample by having a finger pricked.	0	1	2	3	4
2. Having a shot in the upper arm.	0	1	2	3	4
3. Having an anesthetic injection at the dentist.	0	1	2	3	4
4. Having a venipuncture (needle inserted into vein).	0	1	2	3	4
5. Getting an injection in the buttock.	0	1	2	3	4
6. Having one's ears pierced.	0	1	2	3	4
7. Getting a vaccination.	0	1	2	3	4
8. Getting an intravenous injection.	0	1	2	3	4

Figure 2.6 the Injection Phobia Scale – Anxiety Short Form (Olatunji *et al.*, 2010)

A further version of the scale has also been developed for children, described by Oar and colleagues as part of her thesis at Griffiths University in Southeast Queensland, Australia, which is called the Injection Phobia Scale – Child Version (IPS-Anx-C). It is based on the full original 18 item scale, graded on the same five-point Likert Scale, but using child friendly language (Oar *et al.*, 2015) (figure 2.7).

APPENDIX Q INJECTION PHOBIA SCALE – CHILD VERSION (IPS-ANX-C)

Below are a number of statements that boys and girls use to describe their worry about having needles and injections. Read each carefully and circle the number that best describes your worry. There are no right or wrong answers. Please answer all items.

0	1	2	3	4
Not worried	A little bit worried	Some what worried	Very worried	Extremely worried

How worried would you feel about -

1. Giving a blood sample by having your finger pricked.....0 1 2 3 4
2. Having a needle in your arm.....0 1 2 3 4
3. Looking at a picture of a needle.....0 1 2 3 4
4. The smell of a hospital.....0 1 2 3 4
5. Having a numbing injection at the dentist.....0 1 2 3 4
6. Having a blood test (e.g., a needle in your vein and blood withdrawn)..0 1 2 3 4
7. Watching another person have a blood test.....0 1 2 3 4
8. Getting an injection in your bottom.....0 1 2 3 4
9. Looking at a picture of a person having a needle.....0 1 2 3 4
10. Listening to someone talking about injections..... 0 1 2 3 4
11. Looking at and touching the veins in your arm.....0 1 2 3 4
12. Watching a video about a person getting a needle... ..0 1 2 3 4
13. Watching another person getting a needle.....0 1 2 3 4
14. Watching a person in a nurse uniform.....0 1 2 3 4
15. Having your ears pierced.....0 1 2 3 4
16. Getting a vaccination.(e.g., an injection of medicine to stop you from getting sick).....0 1 2 3 4
17. Getting an intravenous injection (e.g., a needle in your vein that connects to tubes and a bag of medicine)0 1 2 3 4

Figure 2.7 the Injection Phobia Scale – Child version (Oar *et al.*, 2015)

The IPS-Anx was initially evaluated by its developers, and colleagues, and reported in their 1992 publication. A further paper was published by Olatunji and colleagues in 2010 reporting their work exploring the psychometric properties in more detail. Öst *et al.*, provided initial data on the IPS-Anx using a sample of 59 adult patients receiving treatment at a psychiatric hospital in Southeast Sweden for simple phobia or injection phobia.

These consisted of 40 patients involved in a study investigating the effect of single session vs multiple session cognitive behavioural therapy on treatment outcomes, and 19 other patients who had been treated before and after the study in question. Patients were aged 18- to 60-years, with a mean age of 28.6 and an average phobia duration of 20 years. Patients completed the IPS-Anx before treatment, one week after completion of treatment and at a one year follow up. Cronbach's alpha was reported as 0.86 for the IPS-Anx, indicating good internal consistency. Clinically significant improvement was calculated using Jacobson's model (Jacobson, Folette and Revenstorf., 1984) and gave a score of 15 (indicating a reduction of 15 points in an individual). The authors also noted its positive association with phobic-associated avoidance, and reactivity related to changes after treatment with behavioural therapy.

Olatunji and colleagues undertook further investigation into the psychometric properties of the IPS-Anx aiming to evaluate the structure, reliability, validity, and clinical relevance (Olatunji *et al.*, 2010). They also developed a shortened form of the measure. All studies recruited students from a large Southern university in America. Their first study recruited 498 undergraduate students. The participants were aged from 17-30 years old, 56% were female. They were asked to complete the IPS-Anx once in a classroom format, as part of a larger study. The Cronbach's alpha was reported as 0.95 indicating excellent internal consistency and supporting the original study. A second study recruited 195 undergraduate participants, 69% of whom were female. The participants, aged from 18-56 years, were asked to complete the IPS-Anx on two separate occasions, 12 weeks apart. The intra-class coefficient is reported as 0.88, indicating strong validity. A third study was undertaken with 319 undergraduate students aged 18-46 years, 61% of whom were female. The students completed the IPS-Anx in a classroom format as part of a larger study. They were also asked to complete the Disgust Propensity and Sensitivity Scale – Revised (DPSS-R by van Overeld *et al.*, 2006), the Padua Inventory-Contamination Fear Subscale (PI by Burns *et al.*, 1996) and the Positive and Negative Affect Schedule (PANAS by Watson, Clark, and Tellegen., 1998). There were strong correlations for scores on the IPS-Anx and DPSS-R ($r = 0.42$) and moderate correlations between scores on the IPS-Anx and the PI ($r = 0.26$) and PANAS (0.27), suggesting good convergent validity.

A fourth study involving 1674 undergraduates aged 17-46 years, 50% of whom were female, investigated predictive validity. Participants were asked to complete the IPS-Anx and were also asked two further questions related to previous fainting episodes and avoidance. Fainting instances were assessed by asking "Have you ever fainted, almost fainted, or felt dizzy during medical procedures such as giving blood or receiving injections?".

Avoidance was assessed by asking “Have you ever avoided, delayed, or put off medical procedures because you were afraid of blood, needles, injections etc?”. A one-way ANOVA revealed statistically significant results ($F(3, 1670)=286.33$, $p<0.001$). Persons with a fainting history, avoidance history, or both scored significantly higher on the measure than those who did not have this history ($P\leq 0.001$).

In the same 2015 thesis that described its development, Oar and colleagues reported the use of the IPS-Anx-C tool by a sample of 24 children and adolescents aged eight to 18 years. The internal reliability was reported as a Cronbach’s alpha of 0.94 suggesting excellent reliability. No further properties were reported.

The IPS-Anx is a specific measure for the assessment of fears around both external and intra-oral needle insertions and their associated medical experiences and mentions a social NBP – ear piercing. This measure explores many relevant scenarios where patients may encounter a NBP and is generalisable to different forms of needle fear. It has been shown to have good validity and reliability and is very comprehensive. However, it is not able to assess physiological symptoms or specific thoughts related to each scenario. It has great potential for use, although unfortunately the paediatric version is not evidenced as having been developed with input from children and is not evaluated as thoroughly. It is hypothesised that the full 18-item measure would be difficult for children to complete due to its length and wording – although this has never been officially explored. This would be an important issue to clarify in future research around needle fear in childhood.

The Self Injection Assessment Questionnaire

The Self Injection Assessment Questionnaire (SAIQ) was produced by © UCB, Braine L’Alleud, Belgium in 2006. It is an eight-item questionnaire which was developed with 12 adult patients aged 24-67 years, with rheumatoid arthritis or Crohn’s disease, to assess their experiences of subcutaneous self-injection (figure 2.8). It is designed to be used pre- and post-injection, and to be suitable for use in clinical studies. The response format uses a five-point Likert scale, where 1 is the worst experience and 5 is the best experience. There is no defined clinically or minimally important difference (© UCB, Braine L’Alleud., Belgium 2006).

Items

1. In general, how afraid are you of needles?

2. In general, how afraid are you of having an injection?

3. How anxious do you feel about giving yourself an injection?

4. How confident are you about giving yourself an injection in the right way?

5. How confident are you about giving yourself an injection in a clean and sterile way?

6. How confident are you about giving yourself an injection safely?

7. Does your current way of taking your medication make you feel in control of your disease?

8. Overall, how satisfied are you with your current way of taking your medication?

Figure 2.8 Self Injection Assessment Questionnaire (© UCB, *Braine L'Alleud*, Belgium 2006)

The psychometric properties of this measure were investigated by Keininger and Coteur in their 2011 publication. Participants were taken from those participating in the multi-centre RAPID 2 trial – a trial investigating the long-term safety and efficacy of certolizumab pegol and methotrexate in the management of rheumatoid arthritis. 97 patients aged 28-69 years (74 female and 23 male) were recruited from America, Poland, and the Czech Republic (ten from USA, 57 from Poland and 30 from the Czech Republic). Patients were asked to complete the SIAQ immediately before their first injection and 20-40 minutes after all self-injections with the trial medication. The injections were planned over three consecutive visits, two weeks apart. Item scores were used to obtain a score from zero to ten for each individual item. Confirmatory factor analyses showed good correlation, with all items having coefficients of less than 0.5 indicating good construct validity. Cronbach's alpha was reported as 0.7 indicating acceptable reliability. The test-retest intraclass coefficient was 0.7, suggesting reasonable validity. No instances of use of the SIAQ in a paediatric population could be found in the literature.

The SIAQ is an efficient tool which appears to be valid and reliable in the measurement of experience of self-injection. It is reasonably brief and is tolerated well by patients. It has not been validated or used in a paediatric population to date. It is not able to measure physiological symptoms or thoughts. It would not be appropriate as a measure of more generalised needle fear, or of other forms of needle fear, due to its specificity. Furthermore, the scenarios assessed within the measure are not relevant to generalised needle fear.

Modified Dental Anxiety Scales

The Modified Dental Anxiety Scale (MDAS) is a short 5-item self-report questionnaire described by Humphris and colleagues (Humphris, Morrison, and Lindsay., 1995). Patients score each item from one – five, where one is least anxious and five is most anxious, the scores of which are combined to give a total level of anxiety (scores range from five – 25). The questionnaire focuses on dental anxiety but has one specific item relating to intra-oral local anaesthetic injections ('If you were about to have a local anaesthetic injection in your gum, above an upper back tooth, how would you feel?'). It is generally accepted that a total score 19 or above indicates high dental anxiety, and each individual item can be screened to assess which aspects cause the patient most concern (figure 2.9).

Modified Dental Anxiety Scale

CAN YOU TELL US HOW ANXIOUS YOU GET, IF AT ALL,
WITH YOUR DENTAL VISIT?

PLEASE INDICATE BY INSERTING AN 'X' IN THE APPROPRIATE BOX

1. **If you went to your Dentist for TREATMENT TOMORROW, how would you feel?**
Not Slightly Fairly Very Extremely
Anxious Anxious Anxious Anxious Anxious

2. **If you were sitting in the WAITING ROOM (waiting for treatment), how would you feel?**
Not Slightly Fairly Very Extremely
Anxious Anxious Anxious Anxious Anxious

3. **If you were about to have a TOOTH DRILLED, how would you feel?**
Not Slightly Fairly Very Extremely
Anxious Anxious Anxious Anxious Anxious

4. **If you were about to have your TEETH SCALED AND POLISHED, how would you feel?**
Not Slightly Fairly Very Extremely
Anxious Anxious Anxious Anxious Anxious

5. **If you were about to have a LOCAL ANAESTHETIC INJECTION in your gum, above an upper back tooth, how would you feel?**
Not Slightly Fairly Very Extremely
Anxious Anxious Anxious Anxious Anxious

Instructions for scoring (remove this section below before copying for use with patients)

The Modified Dental Anxiety Scale. Each item scored as follows:

Not anxious = 1

Slightly anxious = 2

Fairly anxious = 3

Very anxious = 4

Extremely anxious = 5

Total score is a sum of all five items, range 5 to 25: Cut off is 19 or above which indicates a highly dentally anxious patient, possible dentally phobic.

Figure 2.9 the Modified Dental Anxiety Scale (re drawn from Humphris, Morrison, and Lindsay., 1995)

The psychometric properties of the MDAS were reviewed by Humphris, Dyer and Robinson in 2008. Adult participants across the United Kingdom were randomly contacted by telephone using random dialling in postcodes with the aim of obtaining a representative sample. The authors aimed for a sample of 1000. Of the 6937 contacts attempted, 963 were both reached and agreed to participate. Participants were contacted out with normal working hours and were asked about their demographic data prior to being asked the five questions present on the MDAS. The Cronbach's alpha was reported as 0.96, indicating excellent consistency.

There is also a child version of the MDAS, presented by Wong, Humphris, and Lee in 1998, called the Modified Child Dental Anxiety Scale (MCDAS) which contains similar items. However, the response format includes the addition of a faces scale, produced by Howard and Freeman (2007), for easier indication of feelings (figure 2.10).

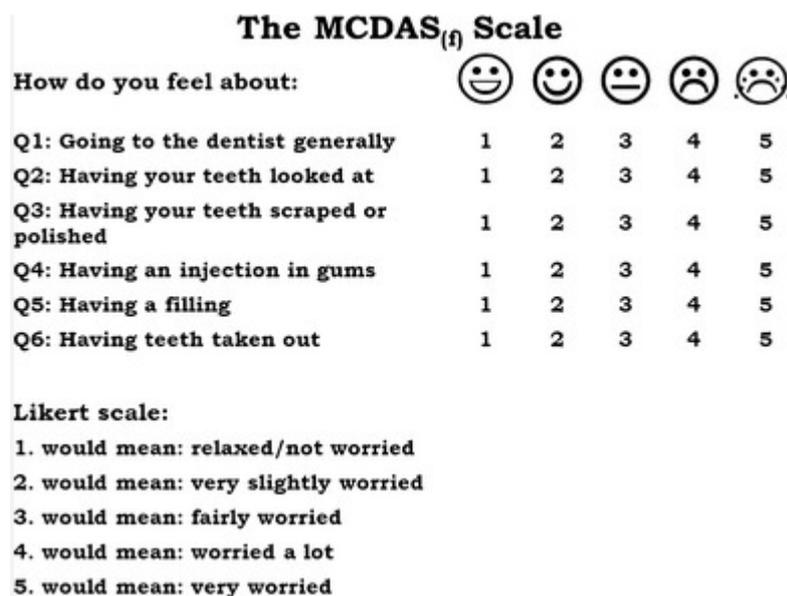


Figure 2.10 the Modified Child Dental Anxiety Scale Faces version (Wong, Humphris, and Lee., 1998)

The psychometric properties of the faces version of the MCDAS were explored by Howard and Freeman. Three studies were undertaken to investigate different aspects (Howard and Freeman., 2007). An initial sample of 240 schoolchildren (181 girls and 59 boys) aged 8-10 years from Greater Belfast, Northern Ireland were recruited for assessment of test-retest validity. The children were asked to complete the faces MCDAS on two occasions, 17 weeks apart. The individual elements of the MCDAS returned intra-class coefficients of 0.6 – 0.83, and there was an overall score of 0.8 indicating good test-retest validity. The second sample of 189 school children (86 girls and 103 boys) aged nine-12 years from Greater Belfast, Northern Ireland, were recruited for investigation of criterion validity. The MCDAS was compared with another established dental fear scale, the Children’s Fear Scale Dental Subscale (CFS-DS). The overall correlation was reported as 0.8, suggesting good criterion validity. A third sample of 200 new patient attenders (97 girls and 103 boys) at a Dental Hospital in Northern Ireland were recruited to investigate the construct validity. Notably, 42% of these children had been referred to the specialist dental service specifically because of their dental anxiety.

The study showed that children who were referred for treatment under General Anaesthetic, an indicator of their likely level of dental anxiety, scored higher using the measure than children who were referred for assessment only, or for standard care.

The cumulative sample of 629 children (364 girls and 265 boys) was used to determine the internal consistency of the faces MCDAS. A Cronbach's alpha of 0.8 is reported, suggesting good internal consistency. The MCDAS and MDAS have been used in studies related to dental anxiety and have included assessment of fear of intra-oral injections based on the single item contained within.

These two measures have been shown to have reasonable validity and reliability and have been utilised in the dental literature as well as in clinical settings. The faces MCDAS was evaluated for use with children aged five -12 years and contains a pictorial faces scale to improve understanding and completion. The scales are efficient at providing baseline dental anxiety scores and could be reasonably considered for measuring change in scores over time. These scales are not appropriate for use in the measurement of needle fear, as they are designed for detection and measurement of dental anxiety rather than needle fear specifically and four of the five include scenarios are not relevant to needle fear.

The Child Anxiety Meter

The Child Anxiety Meter (CAM) was designed by Ersig *et al.*, in 2013 as a single item measure to allow children to convey their level of anxiety at a particular point in time related to medical procedures, by using a continuous scale. Unlike the VAS, this scale is vertical, and is drawn like a thermometer, and children are asked to colour in the scale 'up to the level' of where they feel worried, which is then scored from zero to ten (figure 2.11).

Color the thermometer up to where you FEEL RIGHT NOW.

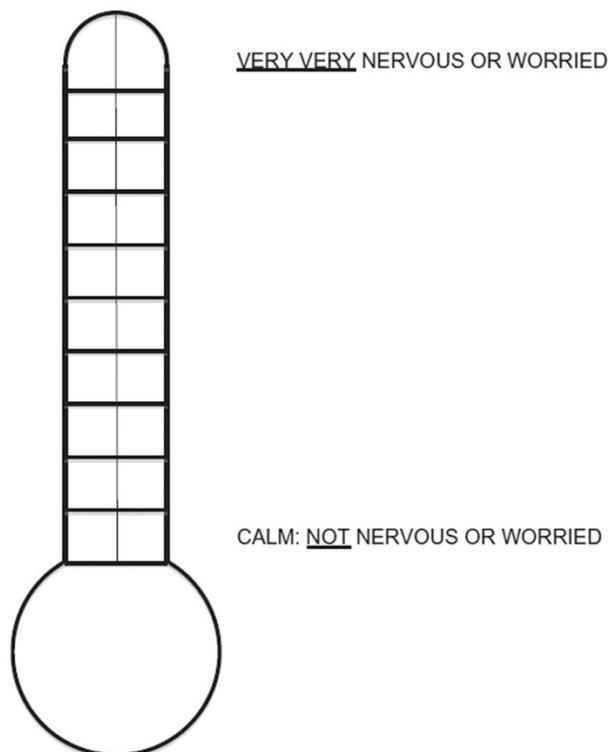


Figure 2.11 the Child Anxiety Meter (Ersig *et al.*, 2013)

The scale was validated by Ersig and colleagues through secondary analysis of a previous study by McCarthy and colleagues where the CAM had been used to record state and trait anxiety in a cohort of children undergoing intravenous access (Ersig *et al.*, 2013; McCarthy *et al.*, 2011). The children were aged four to ten years-old, and of the 542 original participants 421 were eligible for inclusion in the secondary analysis. The study looked only at construct validity. The findings were that correlation coefficients between the scores demonstrated on the CAM tool and the child's behaviour was 0.19, their normal levels of distress were 0.26 and their normal levels of distress related to IV access was 0.25. The authors suggested that this indicates that they are 'significantly correlated', however these figures suggest that in fact although there is a positive correlation it is weak. The authors acknowledged that a secondary analysis has limited their study as they are bound by the restrictions of the data collected for the initial study, and that they have not investigated any other aspects of validity or reliability. They suggest further research is required. No further studies on the psychometric properties of the CAM in English have been completed to date.

The CAM was evaluated for use in a Turkish population by Gerçeker and colleagues (Gerçeker *et al.*, 2018) alongside the CFS. The resulting paper was published in Turkish with the English abstract stating that the study was completed with 135 children aged four to ten in the paediatric services of a university hospital in Turkey.

The authors reported a content validity index of 1.00 for the CAM, a correlation coefficient of 0.99 between the CAM and CFS scales, and negative correlations between the fear scores and child age. There was reported to be a positive relationship with chronic illness. The authors asserted that the CAM is a valid and reliable tool, appropriate for use in the Turkish paediatric population.

The CAM has been used in the published literature in studies investigating children's anxiety related to medical procedures, including two studies investigating needle fear (Gerçeker *et al.*, 2020a; Gerçeker *et al.*, 2020b). The two trials found were RCTs. The reviewed studies used the measurement in paediatric populations only, with ages ranging from four – 17 years old. The studies were all set in secondary healthcare settings in Turkey, with participant numbers ranging from 42–136. All studies also used an additional measurement tool, the Children's Fear Scale for assessing change in needle fear. The studies are discussed in the section discussing the Children's Fear Scale above. It is also worth noting that the primary authors in both studies undertook psychometric evaluation of the CAM for the Turkish population. The CAM has one main advantage as a single item measure in that it could be adapted to any clinical or research question. Researchers thus far do not appear to have confidence in its use for measuring presence and changes in degree of needle fear, evidenced by its lack of use in the published literature. The primary evaluation study is insufficient to suggest that the scale had either good reliability or validity. It has also not been designed specifically for needle fear and it has not been validated as a tool for the measurement of change in levels of needle fear. Although it is developed for use with children, there is no evidence in the literature that children were consulted during its development, and it has not been clarified if children prefer the format of the thermometer compared to a horizontal line (such as the VAS). It is also unable to assess physiological symptoms or thoughts related to scenarios. There is no defined clinically or minimally important difference, meaning it does not have responsiveness to change.

Venham Situational Anxiety Score

The Venham Situational Anxiety Score was first described by Venham. It is an eight-item pictorial measure showing a male child in various states of emotional arousal, which asks children to choose the photo that represents their feelings in a particular situation (Venham., 1979). At that time, a literature review revealed that no appropriate self-report measures for situational anxiety in children existed. The authors therefore aimed to develop a measure for use with children as young as three years. They surmised that children would need to be able to understand the measure and be able to relate it to their inner experience and feelings. A cartoon style report system was therefore suggested.

It was developed for use with children aged three to nine years old and is designed to measure change in emotion at different timepoints (figure 2.12).

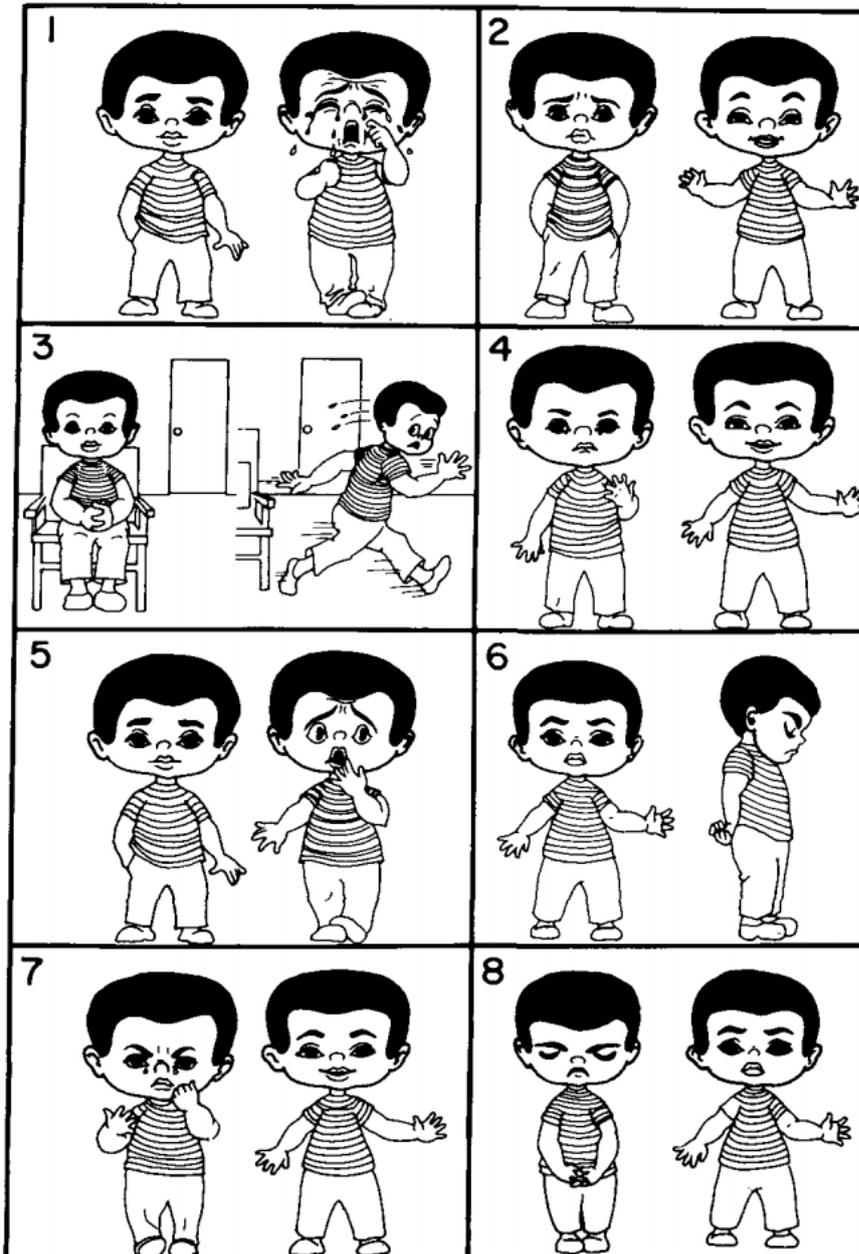


Figure 2.12 the Venham Situational Anxiety Score (Venham., 1979)

The authors constructed a male cartoon figure and devised a scale from neutral to maximum expression of the following emotions: happiness, fear, crying, sadness, anger, fear (flight). The scale was presented to 24 'dentally experienced' children aged three to nine years old. The children were asked to choose the person that represented their feelings, and then attempts were made to correlate this with the child's description and/or observation of their temperament. All the children demonstrated an ability to understand the emotional scale and engage with the measure, based on author observations.

There appeared to be no significant correlation of face chosen with the child's actual age. The measure was used pre- and post-visits to help determine its possible use as a measure for change. The measure was then subject to an item analysis to aid in refining the pictures for use in the final scale.

It was evaluated by Venham and colleagues in the same 1979 paper through the undertaking of two small studies: the first involved 24 children aged three to eight years old attending a public dental clinic for treatment. The children were asked to complete the measure during their assessment and treatment appointments, which occurred at various timepoints. The test-retest validity was reported as a reliability coefficient of 0.7 which suggests good retest validity. The internal reliability was reported to be 0.838 which suggests very good reliability. The second study involved 64 different children aged two to five years also attending the public dental clinic for treatment. The figures are not reported, but the scale is reported to have 'significant correlation' with five other measures of anxiety – heart rate, 'an anxiety rating' which is not further described, basal skin response, human figure drawing and a cooperative behaviour rating. Although this study suggests good reliability and validity of the score, it is based on a very small sample and the results are not clearly presented.

The Venham Situational Anxiety Score is the only measure thus far that appears to have been developed with input from children themselves. It has been used in many studies on anxiety in the published literature with children from a wide range of ages. It was developed in a dental setting and therefore may not be translatable to a more general needle fear. Furthermore, it has not been revalidated for use in a contemporary population, having been developed 45 years ago (at the time of writing in 2024) and it may be that the cartoons are not as easily understood by modern children due to changes in cartoon design trends and new computer technology. Another consideration is the defined white male gender of the figure used in the pictures. This may not represent children who identify as female, or as neutrally gendered, and does not represent children from any other background. This would need to be assessed as part of any future use with the current paediatric population.

2.4.2 Alternative outcome measures

In addition to investigating levels of distress or fear in children during NBPs, studies have also considered other outcome measures.

These have included measures of benefit or success such as whether the child was able to undergo their procedure (McMurtry, Noel, and McGrath., 2011), the length of time required to administer the procedure (Bailey *et al.*, 2020; Chen *et al.*, 2020), the ease of use of the interventional tool (Williams, Morlock, and Feltner., 2010; Freedman, Cox, and Rosebrough., 2008), the satisfaction levels of the healthcare practitioner (Wong, Lui, and Choi., 2019; Jibb *et al.*, 2018) and the satisfaction levels of the parent and/or child (Bailey *et al.*, 2020; Patterson *et al.*, 2019; Wright., 2018; Freedman, Cox, and Rosebrough., 2008).

2.4.3 Summary

The current evidence suggests that there is no single measure of paediatric needle fear which meets the criteria of an 'ideal measure', which is: one designed or developed with children: evaluated for use with children and confirmed as appropriately responsive to change. Of the measurement tools which do exist, the most popular appear to be the Visual Analog Scale (VAS) and the Children's Fear Scale (CFS). This could be due, in part, to the lack of availability of alternative scales. However, there are advantages and disadvantages to the VAS and CFS. Their advantages include being single item measures, which are useful when there is only one aspect being measured. They can be generalised to any situation and procedure, unlike some of the measures such as the Intra-Oral Injection Fear Scale (IOIF-s), Diabetes and the Injection Phobia Scale Anxiety (IPS-Anx) which can only be used for children with specific conditions and/or requiring specific procedures. Neither the VAS or CFS requires any special training, or equipment, for them to be used effectively – unlike a physical measurement of anxiety which requires special equipment and an operator trained to interpret the results, or salivary assessments which would require the services of a laboratory and additional costs. In addition, these two instruments are brief and therefore not time-consuming, and should not require advanced levels of literacy to complete. Both scales allow for a continuous primary outcome, which carries the statistical advantage of requiring a smaller sample size for a fully powered randomised controlled trial. They have both been used in trials investigating the impact of various interventions on needle fear in children and are therefore likely to be accepted by the research community.

They do however have disadvantages. Neither scale has been developed with children themselves as a measure for their needle fear, and each allows a single item to be measured, meaning a more multifaceted assessment of the factors around a child's needle fear cannot be completed. While both show promise as reliable measures, neither's psychometric properties have been convincingly and thoroughly investigated.

The IPS-Anx has great potential as a measure in that it explores many different areas of needle fear, however it is lengthy and written in adult language. The children's version was created without input from children, meaning the language may remain inappropriate or confusing and is not effectively validated for use in a paediatric population.

In summary, the input of children with needle fear is needed to confirm which measures may be most suitable for measuring their fear in future studies. It is particularly important that any instrument can measure change in needle fear in intervention studies that seek to reduce needle fear in this age group.

2.5 How can children and families be involved in the development of tools and resources?

In medicine and associated fields, there has been a positive change in thinking which enables and supports patients to have a more active role in healthcare and decision making. Patients are seen as individuals whose preferences, values and aims must be considered to provide them with the best treatment. Patients are more likely to be involved in shared decision making about their care, and to want to be involved in such decisions, as reflected by the campaign 'no decision about me without me' (Sacristán *et al.*, 2016; Lipkin., 2013; Tinetti and Basch., 2013; Porter., 2010; Laine and Davidoff., 1996).

The development of healthcare resources and the way this is approached has also changed over time. There is a growing body of evidence which suggests that healthcare resources and interventions are more successful and more easily implemented where patients or service users have been involved in their development (Greenhalgh *et al.*, 2019). This section aims to discuss in brief the contexts in which children and families have been involved in the development of healthcare tools and resources.

2.5.1 How have adults been involved in the development of healthcare resources or interventions?

This section aims to identify how adults have previously been involved in resource or intervention development in the published literature.

Identifying priorities for research

It has been recognised that without patient input, research questions (particularly clinical research) while scientifically interesting and/or relevant are not always relevant to patients or other service users. Researchers have suggested that patient involvement in setting research priorities is essential for research to be truly translational (van der Scheer *et al.*, 2017; Sacristán *et al.*, 2016; Elwyn *et al.*, 2010). Translational research is posited to ensure a more effective movement between scientific findings to useful clinical application. As patients are the experts of their experience, their input early in the process of research development could increase the possibility and ease of translation.

The James Lind Alliance in the UK was established in 2004, and brings ‘patients, carers and clinicians together in Priority Setting Partnerships to identify and prioritise the top ten unanswered questions or evidence uncertainties that they agree are the most important’ (www.lindalliance.org). This allows patients and clinicians to contribute to priority setting for the health research agenda in several fields including health interventions and digital technologies. In the United States, the Patient-Centred Outcomes Research Institute (PCORI) was established and authorised by Congress in 2010 with the similar aim of ensuring the identification of ‘critical research questions’ through working with healthcare stakeholders (www.pcori.org).

Through the work of collaborations such as the James Lind Alliance and PCORI, patients can influence the research agenda, to ensure that research into interventions or the development of resources focuses on the areas that patients prioritise (Chalmers *et al.*, 2013).

Development of research proposals

Adults have also been involved in the development of research proposals for healthcare interventions and resource development. Patient and public involvement (PPI) in research is defined by the National Institute for Health and Care Research (NIHR) as ‘research being carried out ‘with’ or ‘by’ members of the public rather than ‘to’, ‘about’ or ‘for’ them. It is an active partnership between patients, carers and members of the public that influences and shapes research’ (NIHR., 2021). They suggest that the public may be involved in research as co-researchers, in identifying priorities (such as with the James Lind Alliance work mentioned above), as members of advising or steering groups, and commenting on study paperwork. People taking part in PPI may or may not also be research participants, which are the people that are recruited to take part in study activities.

Grant review

To conduct research studies, scientists and researchers must apply to a relevant body for funding. This involves submitting their proposal, which is reviewed by a panel to determine whether the research is in line with the priorities of the funding body and will prove beneficial. Patients and members of the public can be members of review panels, allowing them to influence the prioritisation of projects which they feel would be beneficial. Many countries have involved stakeholders in their grant review process for many years including the United States, the Netherlands and the United Kingdom (NIHR 2021; Fleurence *et al.*, 2019; den Oudendam *et al.*, 2019). It is reported that patients and other stakeholders have different perspectives than academics, and through panel discussion can share their thoughts which was found to bring about greater reviewer agreement. Panel chairs were reported to take all views into account when aiding the decision-making process (Rittenbach *et al.*, 2019; Forsythe *et al.*, 2018; Cukor *et al.*, 2016; Fleurence *et al.*, 2014). Reviewers reacted positively to patient input and felt that there was value of input from all reviewer types, although the overall process was lengthier (Oudendam *et al.*, 2019). While this is practically true, it may help reviewers ensure that funds are allocated to studies with higher overall merit and benefit, saving time and money overall.

Co-design and participatory research

Co-design and participatory research describe a process by which patients or other stakeholders are actively and meaningfully involved with healthcare intervention or resource development in more of a partnership role.

A rapid overview of reviews in health co-design was undertaken and published by Slattery, Saeri and Bragge in 2020. They included systematic and narrative review papers of research co-design published between 1964 and 2019. The papers had to include examples of co-design or a description or evaluation of co-design and be published in English (Slattery, Saeri, and Bragge., 2020). In total 26 papers met the inclusion criteria, including 23 reviews, eight systematic reviews, two scoping reviews, four narrative reviews and nine other reviews. The authors determined that researchers tended to adopt differing approaches to co-design, and apply it to different extents, as well as using different terms to describe their approach including participatory design, co-design, and co-production. They concluded that although the evidence on the use of co-design is reasonably limited, the existing evidence suggested that it can benefit researchers, clinicians, research processes and outcomes.

They also described that development of clear and consistent terminology and improved reporting, and evaluation would support better co-design research in the future.

Co-design and other participatory research methods have been used to engage patients in various aspects of healthcare research such as creating recommendations for patient involvement in mental health bedside handovers (Van de Velde *et al.*, 2024), development of a transgender health information resource (Morse *et al.*, 2023) improving the communication of newborn blood spot tests to parents (Chudleigh *et al.*, 2022), development of an oral health intervention by health visitors (Owen *et al.*, 2022), and creation of a virtual reality based exercise game for rehabilitation (Shah *et al.*, 2022). Further discussion of co-design approaches is given in Section 2.5.3.

2.5.2 How have children been involved in the development of healthcare resources or interventions?

This section aims to identify how children have previously been involved in resource or intervention development in the published literature.

Identifying priorities for research

As described above, the James Lind Alliance, which was established in 2004, allows patients and clinicians to contribute to priority setting for the health research agenda in several fields including health interventions and digital technologies. This includes input from children and young people (Narula *et al.*, 2024).

Development of research proposals

Children have likewise been involved in the development of research proposals as part of PPI panels. Some recent examples of NIHR funded healthcare projects which describe the inclusion of children in PPI roles include an obesity prevention intervention programme (Adab *et al.*, 2018), a teacher training intervention to improve mental health in primary school children (Ford *et al.*, 2019), a transition project for young people with attention deficit hyperactivity disorder moving to adult services (Janssens *et al.*, 2020) and comparing eradication regimes for children and adults with cystic fibrosis (Langto Hewer *et al.*, 2021).

Intervention development

There are several examples of children's involvement in healthcare projects such as the development of an augmented reality intervention for children with developmental coordination disorder (Welsby *et al.*, 2024), adaptation of a digital health and well-being programme (Brown, Lord and John., 2023), creation of a programme for children with parents with a mental health disorder (Zechmeister *et al.*, 2022), an age-appropriate psychoeducational resource for children with attention-deficit hyperactivity disorder (Powell *et al.*, 2021), and the development of an adolescent health promotion chatbot (Maenhout *et al.*, 2021).

At the time of writing, no published studies have reported projects where young people had been specifically involved in the development of a resource, intervention or service for paediatric needle fear.

2.5.3 How can families be involved in the development of future healthcare resources or interventions?

Experience Based Co-Design (EBCD)

Experience based co-design (EBCD) is an approach to involving the public in service improvement specifically posited for use in healthcare. It challenges the view of patients as passive recipients of the products of research and introduces the concept of them being integral to the 'improvement and innovation process' (Bate and Robert., 2006). EBCD is described by Bate and Robert as a design process which is user-focused and allows those tasked with improving health services to access the wealth of knowledge and experience of the user to design processes or innovations that will fit into that experience. Experience is defined as 'how well people understand it, how they feel about it while they are using it, how well it fits its purpose, and how well it fits into the context in which they are using it' (Bate and Robert 2006). The reason EBCD is often recommended in healthcare is that it is a structured approach, developed to enable 'staff and patient (or other service users) to co-design services and/or care pathways, together in partnership' (Point of Care Foundation, 2021). It proposes a six-stage process which can be undertaken within a single study. The six stages are: setting up, engaging staff, and gathering experiences, engaging people, and gathering experiences, co-design meeting, small co-design teams and celebration event (Point of Care Foundation, 2021).

Cullingham and colleagues described their use of EBCD in the development of an anxiety intervention for autistic children in their 2024 paper.

The authors had identified that although mental health difficulties are common in this cohort, almost no interventions had been developed with them (Cullingham *et al.*, 2024). Parents of young autistic children had often reported that they felt 'left alone' and wanted to know how to help. The authors selected an existing resource, which they planned to adapt to fit the needs of the cohort. The co-design collaboration, which they termed the 'Expert Reference Group' (ERG) included four parents (autistic and non-autistic) of autistic children with anxiety problems, an autistic young person with experience of anxiety, and two non-autistic clinicians with experience of supporting autistic children with mental health difficulties. The ERG was chaired by the team PPI lead and lead researcher. The ERG members were recruited through local and national parent carer forums and autism charities. Training was provided to members prior to commencing the study. The initial stage of the co-design was evidence gathering, where the group critically evaluated the summary of recommended adaptations for autistic children. Qualitative work was then undertaken, and the key themes presented to the ERG for feedback which was provided to the research team.

Two focus groups were then undertaken with a separate group of parents of autistic children with anxiety, for further insights. The blueprint was then re-defined with the ERG before confirming the final outline of the adapted intervention, and determination of the next steps. The authors reported that both the ERG and research team felt that the collaboration had worked well, stating specifically that the training and support was invaluable in consolidating the group and their confidence, that the ERG was able to operate independently from the research team, productivity was sustained throughout the project, regular meetings were beneficial, and reflection was encouraged throughout to enable flexibility and adaptation as needed. The authors were aware of the risk of power imbalance in co-design collaborations and ensured that the ERG co-chairs from the research team met regularly to reflect on how they may be dismantling or contributing to power imbalances.

The limitations to the study were described as the increased time needed to incorporate the ERG into the study and the additional time needed to integrate the extra perspectives into the project outputs. However, the authors concluded that these had been more than compensated for by the value added by the collaboration. Additionally, they acknowledged that their ERG was of limited diversity, and did not include members from ethnic minority backgrounds, which is a common challenge in UK studies.

EBCD has also been used in the improvement of: communicating the results of newborn blood spot tests to parents (Chudleigh *et al.*, 2022); Breast Services (Boyd *et al.*, 2016), access to diabetes services in rural areas (Cramp 2006), bedside handovers (Hahn-Goldberg., 2015), communication at hospital discharge (Castro, 2018), to improve the pre-treatment pathway for patients with head and neck cancer (Brady, Goodrish, and Roe, 2020).

Co-design

EBCD is only one approach to the involvement of patients and the public in intervention development. Co-design is an emerging method which is being successfully applied to the development of healthcare resources or interventions for children and young people.

There are different types, or approaches, to co-design which are described in the literature and the field of design in healthcare is has been maturing over recent years, developing a vast catalogue of tools and approaches for involving the public. The full catalogue is too broad to review fully within the remit of this thesis, and therefore a review of only the approaches which informed the study are given below.

An article on co-design with young people in the design and development of health technology was published in 2022 by Wheeler and colleagues. The authors state that young people's unmet needs can be identified, validated, and solutions created more effectively where young people are involved meaningfully in research. The article outlines case studies where different approaches to involving families have been incorporated to positive effect. The included studies had used either EBCD, co-design or patient and public involvement and engagement (PPIE). EBCD is defined in the paragraphs above. PPIE is a method defined as research which is done 'with' or 'by' patients or members of the public rather than 'to', 'about', or 'for' them (NIHR Oxford BRC). Co-design is defined as "the creativity of designers and people not trained in design coming together in the design development process" (Sanders and Stappers., 2008). The case studies include the development of a toolkit for juvenile idiopathic arthritis (co-design); addressing the needs of young people with narcolepsy (PPIE and co-design) ; the design of a Chatbot for patients with type 1 diabetes (PPIE and co-design); and creating a device to secure enteral feeding equipment (co-design and EBCD). Each study engaged young people as experts of their experience, along with their parent(s)/carer(s). A variety of activities were designed to suit the aims of the project team and individual needs of the collaborators, allowing them to explore the issues affecting the target population and work with them in the creation of a solution.

In each case, the researchers benefitted from the involvement of young people, and were able to design effective solutions in collaboration.

The authors also suggested some strengths, limitations, and recommended applications for each approach. The strengths of PPIE were identified as the lower cost, lower time commitment, and requirement for very little training to undertake. The limitation is that this method may only reveal immediate priorities, and surface level knowledge. PPIE is recommended for seeking input or guidance at each stage of a study, or as a cheaper and quicker method for identifying unmet needs 'in a largely unexplored context'. The strengths of EBCD were that it is a repeatable method, already widely understood and respected in healthcare, is likely to be lower cost and less time consuming than co-design and needs limited training to undertake. Its limitations are that the ideas are generally small in scale, and there can be power imbalances between participants. EBCD is recommended for use in healthcare service development projects. The strengths of co-design were reported to be its responsiveness and adaptability to context or emerging insights, ability to elicit both surface and deep level knowledge and development of innovative solutions. The limitations to use of co-design are the associated time commitments, costs, and need to involve a designer. This method can also be difficult to evaluate. It is recommended for use where there is a complex context or where there may be different priorities and preferences between multiple stakeholders.

A co-design approach was also adopted by Powell and co-workers (2021) in the development of a psychoeducational activity book for seven- to 11-year-olds about ADHD (Powell *et al.*, 2021). Children were involved in engagement activities to help develop the content of the psychoeducation activity book. Children completed activities such as colouring superheroes, watching videos and playing games. In this way, they were able to share their preferences for the design and content as well as contributing information which could be included. Children shared some similar preferences to the young people in this study in that they wanted to understand where ADHD comes from and how it might affect them and how they can manage their ADHD. They are also able to complete a section of the book, which is personalised about them and their ADHD, which can be separated from the main booklet. This mini booklet can be used to communicate to others such as teachers and friends about their ADHD in a structured non-verbal way. This is in keeping with young people in this study wanting to understand their worries, manage their fear, personalise their use of the resource and communicate with HCPs. Powell and colleagues report that there was good engagement in this cohort with the activities, all participants completed the activities and therefore provided invaluable information to the research book. Children in the ADHD study also expressed a preference for colours and graphics to be incorporated in the booklet.

After testing the booklet with nine parents and 11 children with ADHD, the authors concluded that the psychoeducational book is acceptable, suitable, and engaging to children with ADHD, therefore meeting the aim of the original study. The inclusion of children in the design of the activity book has likely contributed to their success, and the booklet has now been implemented in various NHS trusts, schools, and charities across the UK.

Another health co-design project from recent years was the development of a ChatBot for health promotion in adolescents (Maehout *et al.*, 2021). Adolescents were engaged in a face-to-face group format; however, a different group were recruited for each phase. As part of the first focus group, the adolescents were shown an example of an existing ChatBot, to ensure they understood what a ChatBot was, and help frame discussion. Adolescents involved in the study indicated that they wanted the ChatBot to be tailored to them, and to have confidentiality and privacy in its use. Maehout and colleagues concluded that the inclusion of the adolescents throughout the study, rather than just in the initial stages, had led to the emergence of novel insights which would not have been possible otherwise.

Children with physical disabilities were the focus of a co-design project undertaken by Bolster and colleagues (2021) which aimed to create a tool which would facilitate physical activity in children with physical disabilities (Bolster *et al.*, 2021). The team involved children, parents/carers and numerous stakeholders including clinicians in their collaboration. They applied a double diamond approach (British Design Council, 2004) to plan their activity, with stakeholders being involved in all aspects of the project. One theme which was identified in this project which resonates with the findings of other studies, was the desire for the tools to focus on the needs of the individual child – to be a customisable experience. The authors reflected on the use of co-design as a method, acknowledging that the process had been time consuming. They felt that the time taken had been worth it, as the insights generated by the work contributed a wide overview of expert knowledge (including children as experts in experience). The researchers felt that their collaboration should include conditions where all stakeholders felt and were treated equally, and therefore decided that the authors of quotes would not be documented. This makes it difficult to ascertain how much of the generated information and ideas came from young people themselves, and what came from parents or other adult stakeholders. They concluded that the co-design approach was effective in the exploration of new tools for this cohort, and in obtaining insights from their collaborators.

Co-design strategies complemented by design researchers allow for some additional flexibility and processes which are not possible in more rigidly structured methods.

Generative research methods allow researchers to gain access to tacit participant knowledge and ideas, and for children and young people this can be facilitated using familiar tools and techniques (Süner Pla Cerda and Erbuğ., 2019). Examples given include the use of drawing, clay modelling or drama. Other studies, such as that by Powell and colleagues described above (Powell *et al.*, 2021) have used colouring, videos or playing games. Süner Pla Cerda and Erbuğ described how this form of techniques can empower young people to communicate their ideas and experience in various different dimensions. Co-design also allows for prototyping, where an early version of the planned output can be presented to the participants to help generate further knowledge, ideas and insight, and refine the product until it meets the needs of the users. This prototype is sometimes thought of as the 'beta version' of the output (Isa and Liem., 2020).

2.5.3 Summary

The literature on different techniques suggests that the best form of approach will depend on the nature of the individual project, including not just the research question to be addressed but the funding and time constraints.

EBCD is a beneficial method for those working to develop care pathways and services alongside tight deadlines or with limited budgets, in the development of healthcare services or strategies. It allows for the inclusion of different stakeholders more meaningfully than PPIE alone, and involves users at an early stage rather than a tokenistic input at the end of the project. In more recent years, some researchers have begun to utilise EBCD as a method for the development of resources and interventions as described above (Cullingham *et al.*, 2024; Fylan, *et al.*, 2021). The approach was not designed for use in this way, nor has it been critically evaluated to assess the best method of applying it to this new use.

When used appropriately, the approach has notable benefits, and is a marked improvement compared to previous more tokenistic methods of involving 'service users' in the development of care pathways and services. It has an easy-to-follow layout, which can be led by healthcare professionals without the need for the input of a design researcher. This can make it particularly attractive in NHS settings, where there may be limited time and funding to complete a project. The areas which need careful consideration, are the limitations of the approach. Many may equate EBCD to having similar benefits to co-design when this is not currently the case. Design is a professional practice, like medicine and other professions, which involves a lifetime of learning.

Designers are specifically excluded from EBCD, which lowers the cost and time but also reduces the potential to create innovation and leads to more incremental results. EBCD is notably very rigid and inflexible, meaning the process cannot be easily tailored to meet the needs of the collaborators. It also preserves traditional power dynamics. It is claimed that this can be addressed, but there is a lack of available guidance available to assist with overcoming these dynamics, and where the collaborators have an existing clinical (e.g. doctor and patient) or working (consultant and junior) relationship, which is often the case, this would be very difficult to achieve in practice. There is also an element of EBCD which is non-collaborative, where the research or clinical team will review the results of their interviews/focus groups and observations and decide what is important to share, without any input from the 'user' collaborators. This is important as the research team or clinical team priorities for change may differ to those of their collaborators (the users) and therefore these decisions on what elements to share could prematurely block potential areas or avenues for innovation.

Conversely, co-design is a method which benefits from the input of design researchers, leading to both creative methods of including and supporting participant engagement and the development of more innovative outputs. It can be useful for anyone working with a complex context, where a person may be affected in different ways or aspects of their life, or where there are numerous stakeholders to consider. The main limitation is that it is, however, costly and time consuming in comparison with EBCD.

The methodology, and its evidence base and rationale, in each case must be carefully matched against the research project to determine which is most appropriate for that research context.

Many of these studies have some similarities in their findings, despite focusing on a diversity of healthcare needs and populations from around the world. For example, young people have been supported through appropriate activities which have empowered them to engage, contribute meaningfully to the research and provide useful insights. Researchers have appreciated the benefit of using a design methodology and have taken different approaches to tailor the process to their needs and topic area.

2.6 Summary

Following a wide review of the literature relating to needle fear in children, the following key points can be made:

1. Needle fear is common in childhood and adolescence
2. Needle fear has the potential to cause negative impacts on children's wellbeing and health across their life course
3. Needle fear is a clinically important condition in children
4. No standardised and validated measure exists for assessing needle fear in childhood
5. Self-reported measurement tools are the most reliable and valid approach
6. No self-help management strategy for needle fear exists which has been developed with input from children and young people
7. There is strong evidence that meaningful involvement enhances the impact and sustainability of new interventions
8. There is evidence that co-design approaches can support the meaningful involvement of children, young people, families, and healthcare providers in the development of new interventions
9. There are recognised gaps in the available research which suggest that areas for future enquiry should include:
 - a. Exploration of the factors which contribute to the development and maintenance of needle fear in childhood and adolescence
 - b. Development and psychometric testing of a child-appropriate measurement tool for needle fear
 - c. Development of self-help resources to address child and adolescent needle fear with input from the target population

Chapter Three

3. Aims and Objectives

3.1 Rationale, aims and objectives for research presented in this thesis

Literature

As presented in the narrative literature review in Chapter Two, the current literature around needle fear in children focuses mainly on management options to reduce pain and fear of needles. There is a paucity of literature surrounding the development of needle fear, although it is widely accepted that needle fear is likely to develop similarly to other specific fears. The factors which contribute to the maintenance of needle fear, particularly through to adolescence and adulthood are poorly understood.

The measures used to record needle fear vary widely, with no singular preferred or superior measure emerging. Despite many of the measures used being suitable for children to use for self-reporting, most published studies appear to include or rely solely upon proxy reporting, despite the known limitations of this approach.

Previous research into the management of paediatric needle fear has focused mostly on established techniques such as professionally provided therapy, distraction techniques and relaxation exercises. More recent studies seek to assess the impact of novel virtual methods of reducing needle fear, particularly with virtual reality tools. Despite recent advances, there are still limited resources which have been developed with children specifically to address their needle fear. There are also no self-help tools available to specifically address the unhelpful thoughts and feelings associated with needle fear.

The programme of work planned for this PhD thesis, sought to address some of these gaps in the literature. Specifically, gaining understanding of the factors which can influence development and maintenance of childhood needle fear, and aims to develop, with children and adolescents themselves, a resource for the management of needle fear.

Patient and Public Involvement (PPI)

A pilot PPI group, composed of young people aged ten – 17 years old, parent representatives and healthcare professionals was consulted prior to the submission of the project for funding consideration. They were recruited through known contacts, with members having participated as PPI representatives in other research projects previously. The initial consultation focused on the perceived need for a project to create a resource for childhood needle fear, and to address the gaps in the literature. Young people felt strongly that needle fear was impactful to them, and caused them difficulty accepting procedures. Some young people also expressed that this fear could be embarrassing, particularly during school vaccinations. Young people were unsure where to go for support, and agreed that there was a need for an easily accessed resource to provide this support. Parents and healthcare professionals also noted that some young people were disadvantaged by their needle fear, through longer waiting times particularly, and HCPs in particular highlighted challenges for managing these patients, especially as they did not meet the criteria to be seen in psychology services locally. Young people were also instrumental in defining the target age group, as they reported that after their pre-school vaccines most of them had not undergone a needle-based procedure until their planned school vaccinations in Year 8 (11–12-year-olds). Therefore the resource should focus on supporting young people from 11-16 years, as they felt 17- and 18-year-olds would need something more ‘adult’. They agreed that young people should continue to be involved in all aspects of the project, and a PPI group would be consulted at each stage. This PPI group also helped develop the project short name (No Need(le) To Worry) and logo, with the aid of a graphic designer TH.

The aims and objectives of this research project were as follows:

Aims:

1. To explore the views and experiences of children, young people and their families about the development and maintenance of needle fear
2. To explore the preferences of children, young people and their families for a self-help resource aimed at addressing their needle fear
3. To develop and conduct a feasibility study of a self-help resource to reduce needle fear in children and adolescents to inform a future definitive study

Objectives:

1. Undertake qualitative interviews with children, young people, and their families to gain a meaningful insight into their experiences of needle fear, and preferences for a self-help resource to address needle fear
2. Use a co-design approach with children, carers, and healthcare professionals to develop a self-help resource
3. Conduct an uncontrolled feasibility study to address the following uncertainties:
 - a. The most appropriate self-report measure of needle fear (which will be the primary outcome for the future trial)
 - b. The perceptions of key stakeholders (such as phlebotomists, dentists, anaesthetists, research nurses) on the resource and on their willingness to recruit participants
 - c. Feasibility of recruitment
 - d. Retention and completion rates
 - e. Acceptability of the resource to children and their parents, and their willingness to be recruited

The research was undertaken in three stages. Section 3.2 – 3.4 describes the specific rationale for each stage in detail.

3.2 Stage One - Qualitative enquiry to explore children's experiences of needle fear and preferences for a self-help resource

3.2.1 Rationale

The initial stage of the project was to conduct qualitative interviews, which then informed a co-design approach to develop a self-help CBT resource. Involving patients and healthcare professionals in the design of healthcare interventions helps to ensure that the product is both acceptable and fit for purpose in its intended setting (Green *et al.*, 2018). A recent review has stressed the importance of involving young people at the earliest possible stage in developing resources which will be aimed at them (Bevan Jones *et al.*, 2020).

A qualitative methodology was chosen as it is the most appropriate design for gaining insight into 'why' people feel a certain way or engage in certain behaviours.

It is more exploratory in nature than quantitative research and aids researchers in gaining an understanding of people's underlying opinions, motivations, and reasons. It is generally designed to be much less structured and can therefore allow participants to guide the process and allow access to a greater depth of information (Rosenthal, 2016; Creswell and Poth, 2017). This is appropriate for exploring the views, experiences and preferences of the children, young people, and their families.

3.3 Stage Two - Co-design of self-help resource

3.3.1 Rationale

As asserted in Chapter Two, there is a general movement to support patients in being more engaged and involved in healthcare, including the development of new tools, treatments, and resources (Sacristán *et al.*, 2016; Tinetti and Basch., 2013; Lipkin., 2013; Porter., 2006; Laine and Davidoff., 1996). Broadly speaking, service users (usually patients or their families) and stakeholders are being acknowledged as having novel insights and practical information that can be beneficial to production processes (Robert *et al.*, 2021). Emerging evidence suggests that where these service users and stakeholders are involved in their development, such as in a co-design process, healthcare resources and interventions are more successful, contextually appropriate, and easily implemented. Service users can then benefit from interventions and services which better meet their needs (Steen, Manschot, and De Koning., 2011; Alam., 2002).

3.4 Stage Three - Feasibility study of developed resource to address key uncertainties

3.4.1 Rationale

The final stage of the project was to conduct a feasibility study of the developed resource. A feasibility study was chosen to provide methodological evidence for the design of a future randomised controlled trial (RCT). The feasibility study will inform the main trial design, through identification of key issues or barriers to implementation and processes. This will allow these issues and barriers to be mitigated in future evaluations, which could otherwise limit its successful delivery. Given the cost and time impact of running RCTs, it is essential that these are planned carefully (Blatch-Jones, Pek, and Kirkpatrick., 2018).

Another option would have been to undertake a small external pilot study, which would additionally allow for evaluation of the outcomes of interest, and assessment of randomisation and attrition rates. The reason this approach has not been taken is due to the variability of correlation between the results obtained in external pilot trials to the full-scale trial.

Cooper and colleagues (2003) undertook a review and reported the usefulness of publicly funded pilot trials in predicting randomisation and attrition rates in their definitive study. They reported that there was high variability between the rates of external pilot studies and their associated full trials and recommended these be undertaken with caution, with internal pilot trials being much more appropriate and accurate. Given the additional cost and time required to undertake randomised pilot trials, it was therefore not appropriate to undertake an external pilot study for this project due to the lack of accurate additional information that would be obtained (Cooper *et al.*, 2003).

Chapter Four

4. Stage One - Qualitative enquiry to explore children's experiences of needle fear and preferences for a self-help resource

4.1 Introduction

As discussed in previous Chapters, the research and literature focusing on needle fear in childhood is scarce. Little is presently known about the definitive factors which prevent and mitigate development of needle fear.

To develop a resource for this target population, it is important that these factors are explored, and that their preferences for the format and style of the resource is considered to ensure the resulting resource is fit for purpose, contextually appropriate and acceptable to children with needle fear (Bevan Jones *et al.*, 2020; Green *et al.*, 2018).

The findings from Stage One were used to gain insight into the development and maintenance of needle fear in children, and to inform the co-design of the resource.

A PPI group was recruited through known research and clinical contacts, and included young people aged 11-16 years old and parent representatives. This group was consulted throughout the study. The core group consisted of six young people (four female and two male) and five parent representatives (four female and one male). Additional ad hoc PPI input was sought where needed or appropriate. The role of the PPI group was to advise on the study design, associated activities and paperwork, recruitment strategies, and dissemination plan. They were not formal participants in the study at any time. The specific contributions made are described within each Chapter.

4.2 Aims and objectives

The aims and objectives of Stage One were:

1. To explore the views and experiences of children, young people and their families about the development and maintenance of needle fear

2. To explore the preferences of children, young people and their families for a self-help resource aimed at addressing their needle fear
3. Undertake qualitative interviews with children, young people, and their families to gain a meaningful insight into their experiences of needle fear, and preferences for a self-help resource to address needle fear

This would be achieved through:

- Conduction of semi-structured interviews with children with needle fear and their parents or carers
- Use of a CBT model as a framework to inform the qualitative interviews to understand specific aspects of children's experience of needle fear

4.3 Ethical approval

Ethical approval for this stage of the project was granted by the London - Westminster Research Ethics Committee (01/12/22 ref: 22/PR/1451)

4.4 Method

4.4.1 Study design

This section was written with reference to the Consolidated Criteria for Reporting Qualitative Research Checklist (Tong *et al.*, 2007).

In Stage One, a qualitative methodology was applied, with a constructivist epistemology and a pragmatic ontology. Constructivism suggests that a person creates their own understanding of the world through their lived experience and personal reflection of those experiences. A pragmatic ontology likewise views knowledge as being constructed on real-life experiences and is interested not only on the foundation of this knowledge, but its usefulness in practical contexts. Both stances allow and expect marked differences in the experiences and subsequent attribution of meaning between different participants. These stances informed the design of this stage of the study through appreciation of the importance of this subjectivity and understanding the importance of context. A semi-structured interview approach was determined as most appropriate as it allows for acquisition of specific information desired by researchers, while supporting open dialogue.

The theoretical framework used to develop the topic guide and map initial findings is based on the Five Areas™ model of CBT (Williams and Garland., 2002). This model considers the areas of thoughts, physical symptoms, behaviour, emotional state, and situational factors (external factors) in relation to the individual. An example is shown in figure 4.1.

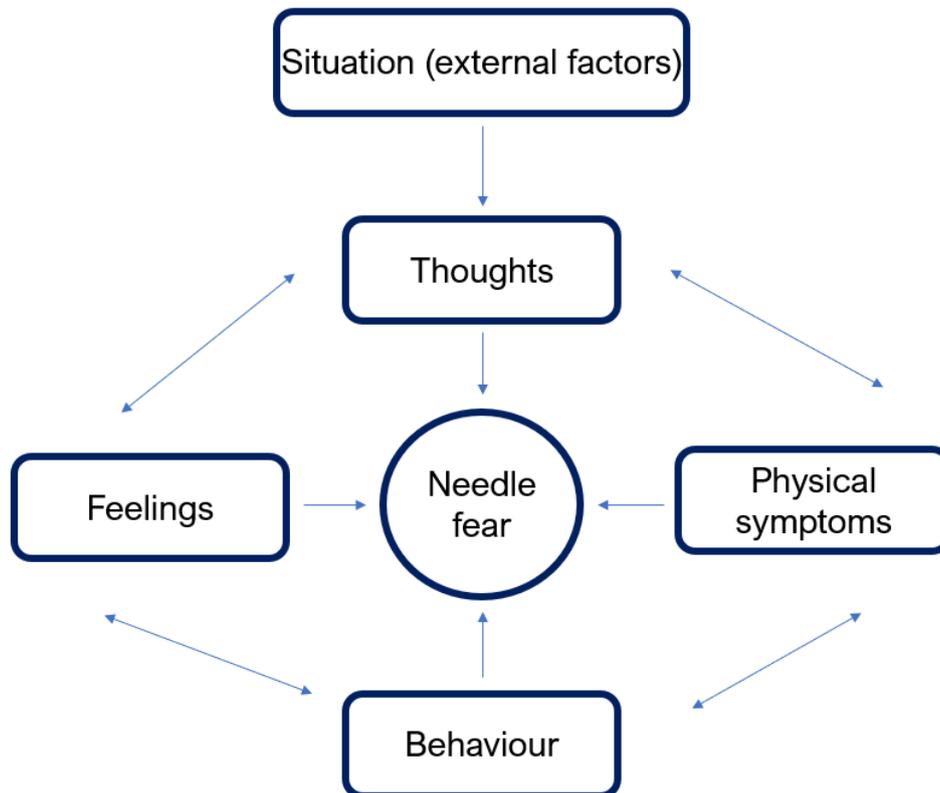


Figure 4.1 the Five Areas Model as applied to needle fear, adapted from Williams and Garland 2002

The application of this framework allowed for the consideration of all these factors, particularly children’s perceptions of anxiety and specific situations, in the exploration of their experiences of needle fear.

Interviews were conducted by the author, a lone female researcher (FS). The researcher is a female clinical trainee in Paediatric Dentistry with a master’s in clinical research. She additionally completed a NatCen learning course on Depth Interviewing Skills prior to the study commencing. At the time of undertaking the interviews, she was employed as a research fellow at the University of Sheffield.

The researcher did not know the participants prior to recruitment to the study.

Participants were informed of the study details as per their participant information sheets and were advised that the researcher's goals were to create a resource to help young people with needle fear. The researcher had no previous involvement in research with this cohort which would have influenced their behaviour or motivations during the interview but did have clinical experience of the management of young people with needle fear. This may have impacted her approach, as she was aware of the potential for the topic to cause distress.

4.4.2 Participants

Eligible participants were children aged 11-16 years old with needle fear and their parents or carers. This age range was selected to fit with the target age range for the resource. A PPI group, consisting of young people aged 11-16 years old and parent representatives was consulted and aided in the creation of the consent and participant information sheets for both young people and parents. Presence or absence of needle fear was determined through a screening question. The screening question was defined by the PPI group and stated, 'how do you feel when you need to have a needle?'. Young people could choose from four options: very worried, a little bit worried, not at all worried or would rather not say. Young people choosing either 'very' or 'a little bit' worried were eligible for inclusion. Young people were excluded if they did not fit the age criteria, did not have needle fear, or did not have the capacity to assent to participate. Participants were directly recruited from two secondary care settings: paediatric dentistry and a children's hospital. Participants were identified and approached in the first instance by a clinician managing their care. The nature and purpose of the study was discussed verbally, with both the children and their parent/carer given a written information sheet where they had attended in person.

A purposive sample was sought to ensure a wide range of child and parental perspectives could be explored (Robinson 2013). The key socio-demographic characteristics were gender, age, setting, area-based deprivation (based on postcode) and ethnicity. Practically participants were identified as they presented to clinical settings and recruited consecutively. The classification for ethnicity was taken from the categories used by the Office of National Statistics (ONS) during national surveys. Children were able to choose whether to be interviewed with, or separately from, their parents and could revisit this decision at any stage.

4.4.3 Data collection

Semi-structured interviews were conducted with participants over an eight-month period. Participants were able to opt to undertake interviews face to face or online. For those who selected face to face, they were given the choice of having the interview at the clinic, within the University of Sheffield, or another appropriate venue – such as their own home. Participants were provided with refreshments and offered reimbursement of reasonable travel expenses.

A topic guide was developed to support the interviews, using the Five Areas Model of CBT as a guide (Williams and Garland, 2002). The initial topic guides are attached in appendices 4 and 5. The topic guide was created by FS in the first instance, with input from her primary supervisor (ZM). It was then subject to review and modification following input from a qualified clinical psychologist (PW) followed by two additional supervisors (HR and DW). Young people and parents from the PPI panel were invited to review the document and make final suggestions regarding acceptability and language which were incorporated into the final versions shown in appendices 6 and 7. The topic guide was used within the interviews to stimulate and guide conversation, with scope for exploration of additional ideas which emerged. Once participants had finished making suggestions for the resource, they were shown existing resources. All participants were shown existing resources for dental anxiety called *Your Teeth You are in Control (Living Life To The Full™)*. These are attached as appendix 8. A second resource, a webpage about needle phobia 'Vaccination Fear and Anxiety' from the Sheffield Children's Hospital which was published online during the interviews, was shown to participants nine-13. These are attached as appendix 9.

Supportive materials such as arts, crafts and other innovative techniques were offered to complement verbal interviews and help children express their thoughts, as some children are known to find them difficult to verbalise (Clark, 2005). At completion of interview, each participant was provided with a £10 gift voucher to thank them for their time. The interviews were audio-recorded on a digital sound recorder (*Olympus U.K and Ireland WS-853*) and transcribed verbatim. Interviews one and two were transcribed by FN, all others by a professional external company Dictate2Us (Manchester UK). Personal details were removed prior to sending for transcription, with pseudonyms used during the interviews. Participants were recruited until no new ideas were obtained, as is appropriate for qualitative explorations (Creswell, 2013).

4.4.4 Analysis

Analysis was conducted concurrently to recruitment and data collection. A framework approach was employed using the Five Areas Model initially to guide the analysis (Ritchie and Lewis., 2003). A combination of inductive (data driven) and deductive (theory driven) coding and theme development were employed (Fereday and Muir-Cochrane., 2006). The following steps were taken:

1. Transcription of data by Dictate2us (external company)
2. Familiarisation with the interview transcripts
3. Coding and development of a working framework for analysis
4. Application of the developed framework to the dataset
5. Charting of the data into the framework matrix
6. Interpretation of findings

The researcher met with another experienced qualitative researcher (ZM) to review and debrief following completion of an initial three interviews.

Participants who agreed to be contacted and members of the PPI panel were invited to comment on the analysis, to ensure they agreed with the interpretation of the data and to support analysis, as adults often misinterpret children's meaning (Huang *et al.*, 2014). Researchers FS and ZM independently read and reviewed transcripts to identify important and recurring ideas within the data. Any disagreements were resolved through discussion. The data were organised into themes, some of which were categorised under one of the domains of the Five Areas Model where appropriate. Each interview was reviewed, labelled, and indexed into a Microsoft Excel 365 database (Washington, Microsoft Corporation).

A framework was developed based on the first five interviews, with evidence to support each subtheme traced to the original transcript from each participant (Smith and Freeman., 2010). For each subsequent interview, ongoing analysis and discussion were undertaken to further refine each theme and subtheme, until a stage was reached where no new ideas or themes could be constructed. At this stage, data collection was deemed to be sufficient, and recruitment ceased.

Data relating to socio-demographic variables were transferred manually to a separate Microsoft Excel Office 365 Database (Washington, Microsoft Corporation) with simple descriptive analysis undertaken. To determine the deprivation decile, postcode data was converted using the postcode conversion function of the Ministry of Housing, Communities and Local Government website, which is based on postcode data from the English indices of deprivation 2019 with one being most and ten being least deprived.

4.5 Results

4.5.1 Sociodemographic variables

Overall, 204 families agreed to be screened, with 62 being eligible to take part following screening. Interviews were conducted with 13 children and 14 parents between March and September 2023. The families who declined to participate were asked to explain their decision where this was possible and felt to be appropriate. Although reasons for declining were not always provided, some explanations included: ongoing issues concerning parent rights for the child (meaning ambiguity about who might consent), difficulty expressing opinions and the child being upset following their appointment. The age of the included children ranged from 11–15 years old. Eight participants were female.

Although all participants were recruited from services within Sheffield, participants came from a geographic area which included Nottinghamshire. All interviews were held in the participants own home, and in all but one case children were interviewed at the same time as their parent/carer (one parent had a scheduling conflict and was interviewed on a separate occasion). One family opted for both the mother and father to participate in the interview. The characteristics of the child participants are detailed in table 4.1. Most of the parent participants were female, with only two males. None of the participants were known to the researcher (FS) prior to conducting the interviews.

Interview	Gender	Age (years)	Deprivation quintile	Ethnicity	Pseudonym
1	F	15	2	White British	Emily
	F	Parent	2	White British	Babs
	M	Parent	2	White British	Frank
2	F	11	5	White British	Chris
	M	Parent	5	White British	John
3	F	12	1	Mixed Asian/European	Lia
	F	Parent	1	White European	Holly
4	M	12	6	White British	Ryan
	F	Parent	6	White British	Isabelle
5	M	14	9	White British	Mina
	F	Parent	9	White British	Gertrude
6	F	13	10	White British	Clara
	F	Parent	10	White British	Kate
7	M	11	9	White British	Batman
	F	Parent	9	White British	Trisha
8	M	16	7	White British	Leon
	F		7	White British	Lucy
9	F	14	5	White European/British	Maria
	F	Parent		White European	Martha
10	F	11	7	White British	Rosie
	F	Parent	7	White British	Peppa
11	F	11	6	White British	Tigger
	F	Parent	6	White British	Piglet
12	F	12	9	White British	Miranda
	F	Parent	9	White Irish	Patricia

Table 4.1 Stage One interview participant characteristics

4.5.2 Themes

As described previously, both the topic guide utilised during the interviews and the subsequent thematic analysis were guided by the Five Areas™ model of CBT (Williams and Garland, 2002).

The findings related to needle fear are described firstly in the context of the Five Areas™ model with a selection of quotes to illustrate each, before exploring the preferences about the resources.

Figure 4.2 maps the main factors related to specific domains in the Five Areas Model™.

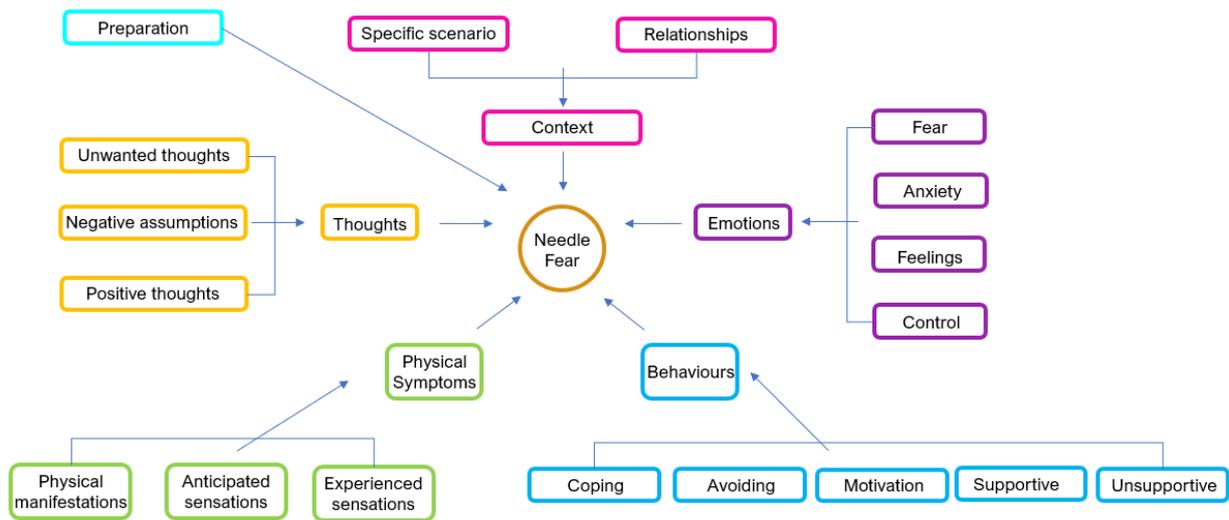


Figure 4.2 Diagram mapping children’s experiences of needle fear to the Five Areas™ model (Williams and Garland., 2002).

The domains of the Five Areas model are: context, emotions, behaviours, physical symptoms, and thoughts. Within each domain, the findings have been categorised into themes, which are described in turn below.

4.5.2.1 Context

This domain relates to circumstances which contribute to the setting and may influence the young person’s fear of needles.

Important themes in this domain were: specific scenarios and relationships.

Specific scenarios

Within this theme, young people discussed contexts or situations which they felt had impacted on their fear of needles – either positively or negatively. These specific situations included the gap between procedures, previous experiences, the setting, or the site of their procedure.

Some young people felt that their needle fear was related to the large gap in their lives between NBPs.

“I was probably nervous because I’ve not had one in like a long time”

Miranda, 12-year-old (yo) female

“There was a big gap between vaccinations because you’ve got vaccinations where you were a baby and there then is a big gap, and then you had vaccination this year and suddenly, you know, we are surprised because you’re scared of needles. We didn’t know about it before because there was no need for needles really”

Maria’s mother

Some parents believed an experience earlier in childhood was the most likely cause.

“I was like manhandling, rugby tackling her, and they said lift her dress up and it was like whack in the side”

Emily’s Father

“Subconsciously I think you do remember things without realising it as we all know, and then you see that as a bad thing and not a good thing”

Emily’s Mother

There was a range of views expressed about the influence of the setting in which treatment was received, with some young people favouring school-based procedures due to the shared experience with peers, while others found the school setting particularly difficult.

“I think having it in the group session just makes it less scary because everybody’s having it, I guess”

Leon, 16yo male

“Recently I’m not very good at them because when I have them at school, I’m horrified of them”

Maria, 14yo female

Others described their secondary care dental setting as favourable for specific reasons, such as being given information or additional support which was implied not to have been their previous experience.

“Once I’m there it’s like, it’s alright because they tell me what’s going to happen. Well, this is at the, like your dentist. The children’s one”
Ryan, 12yo male

“Not when I was with Jen [secondary care dentist] because I had the happy air [inhalation sedation] and the numbing cream so it didn’t actually hurt at all”
Rosie, 11yo female

For some, rather than the specific setting, there were other factors within the setting which had influenced their fear – such as being able to see the treatment needle.

“It was broken [tooth] and it hurt a load and they pulled it out, and they said ‘close your eyes’ but of course I was six, so I didn’t, and I saw this massive needle”
Ryan, 12yo male

“I saw the actual needle, it put me off. It was very long, and I felt like it was going to go deep”
Chris, 11yo female

The number of healthcare professionals involved in the different settings also seemed to bother some young people.

“It was just a single room with a lovely lady, and obviously it’s better than having everything around you”
Maria’s mother

“There was quite a lot of nurses for like just one person. It felt a bit like overcrowded”
Miranda, 12yo female

It was also clear that for some young people it is not just the setting of treatment but what procedures were going to follow their NBP, and the site of the NBP on their body.

“It’s not just the needle that hurts, it’s like actually having them removed [teeth]”
Miranda, 12yo female

“I would feel very stressed because I just don’t like the idea of something being stuck into my body, um, or someone taking blood out of me”
Chris, 11yo female

“He said before that he’d rather have them in his mouth than in his arm”

Mina’s mother

For other young people, these situations did not seem to have specific impacts. Some participants could not identify a specific event which they believed had contributed to their current fear, although it may be difficult for parents and young people to recall instances from several years previous which may have contributed to or caused the fear of needles.

“I don’t think anything’s made me really scared of them”

Clara, 13yo female

“You’ve always not liked the idea, but I don’t think you’ve had a core experience such as frightened you. In fact, to be honest love I think you weren’t frightened of it a few years back, I think you’ve got more anxious of it as you’ve got older”

Chris’ Father

This highlights that there are multiple aspects of treatment type, setting and environment which may influence needle fear in these young people.

Relationships

Young people shared that their relationships with others often played a role in their feelings about needles, and their success in receiving treatment. Broadly, young people described supportive and unsupportive relationship factors from their parents and healthcare professionals. Young people referred to the behaviour of healthcare professionals rather than parents, suggesting that in this age range, healthcare professionals play an integral role in their experience of needle fear.

Parents also discussed their own culture or upbringing in relation to needles, which is described in a separate section below.

Supportive factors

These were factors that some young people felt positively impacted their experiences or better enabled them to accept care, which appeared to be connected to having developed a relationship where the adult appreciated or understood their fear and took steps to support them. These steps included hiding the needle from sight, providing them with information to allow them to understand and prepare for treatment and being empathetic and supporting them through the procedure.

“They just like talk to me and calm me down, they stop me from looking at the needles and like try not to get the needles in front of me, which helps because then I won’t freak out”

Emily, 15yo female

“Sometimes when they talk to everyone who’s doing it, they’re like really nice and they’re friendly and it helps a lot I think”

Clara, 14yo female

“Once I’m there it’s like, it’s alright because they tell me what’s going to happen”

Ryan, 11yo male

“I had two people and I got to hold Mum’s hand”

Rosie, 11yo female

Parents also commented on the supportive behaviour healthcare professionals had exhibited at appointments which they had observed.

“I remember now that’s just come back to me, when [other daughter] did come to Paediatrics [secondary care], you never see the needle in your hand there. You never see the local anaesthetic needle. They don’t see it as a patient, and I don’t remember seeing it”

Clara’s Mother

Unsupportive factors

There were also factors that young people or parents felt negatively impacted their feelings or caused a barrier to them accepting care. This seemed to be connected to a poor relationship with the adult, where they failed to recognise their fear of needles or to appreciate the extent of the fear. Young people shared experiences where they had been rushed, given misleading information, or received care from a healthcare professional who had a poor understanding of how to manage anxiety. This suggests that a poor relationship with the treatment provider may be influential.

They seemed to particularly dislike when they perceived that information had been withheld from them, or where things had been misrepresented by healthcare professionals.

“Sometimes the doctor says right, so this is the needle I’m going to be using, it’s only a small one – look I can touch it – but they’re not actually touching it”

Peppa, 11yo female

“You know you’re going to feel some things, so I don’t really like when they say I’m not going to feel a thing”

Lia, 12yo female

“You can feel it and they didn’t tell me like what they were doing and how long it would take or anything”

Ryan, 12yo male

Some participants felt hurried or rushed during their appointments, which increased their worries or made them feel that the healthcare professional was not interested in their care.

“Said like ‘Oh it’s not very fair on the other children that need to come and have theirs as well”

Miranda, 12yo

“Trying to rush me and tell me that like people are waiting outside and I need to hurry up because, erm, that happened once to me before, and that just kind of made me feel a bit stressed then”

Chris, 11yo female

“The local dentist tried to do the treatment, but he literally said he hasn’t got time to deal with anyone who’s got nervousness, he wants you in and out.... so, he’s not bothered if you’re not gonna sit there”

Emily’s Father

Young people with additional needs, such as autism spectrum disorder, shared additional frustrations.

“They just come out in front of you and just say it. And like even if they’re not doing it yet, you are doing it you’re thinking about doing it. So, if you do it, I’m already worrying about it”

Tigger, 11yo female

“They got all this time to build up, build up, the anxiety builds up to the point where it’s just like, no. And instead, it’s the people at home that have to pick up those pieces. For me I don’t think it’s fair.”

Tiggers Mother

Young people also described how their parent's behaviour could be unhelpful at times, where the parent had failed to appreciate their support needs.

"It's almost annoying when they go 'oh you'll be fine, oh you'll be fine'. It just makes me feel a bit like, I know, you don't have to keep on telling me because if you keep on telling me it's getting annoying"

Batman, 11yo male

Parents also shared their experience of seeing other parents in situations where they felt the adult had not supported their child effectively.

"If parents will play to that anxiety, it's not helpful for the child"

Lia's Mother

"A lot of parents in that reception when we were there the first time, they couldn't be bothered to be here, it was wasting time out their day and they were like, oh I hope they get it, out and done"

Emily's Father

This highlights that a child's relationship with the adults present during their procedures may impact on their experience of needle fear, and in turn affect how supported they feel during treatment. It seems clear that the approach of healthcare professionals can be very impactful on young people's experiences of needle fear.

Parent factors

Parents described their own feelings towards accepting treatment with needles, shaped by their upbringing and culture. Parents had experienced care in a period or culture where it appears there was poor appreciation of childhood anxieties and little support was offered, with children expected to simply behave and do as they were instructed.

"When we was growing up it was just you had to do it and that was it and that was the end of it"

Emily's father

"I'm Polish, and you know Polish people they just get on with stuff, so I don't see the reason why I need to tell her. She just needs to get on with stuff, I know it sounds maybe harsh"

Maria's mother

These childhood experiences may impact on how these parents interact with and manage their own children's anxieties.

Other parents described how they tried to support their children through procedures and empathise with their children's worry.

"Identify those thoughts which are very frightening and trying to diffuse them because they kind of make things worse"

Chris' Father

"We know it's tough for her anyway, so we just try and go with the flow isn't it, just distract her by talking about different things, making jokes about everything and just, yeah, general stuff like that"

Emily's Father

The level of empathy a parent can feel for their child may have a direct influence on their ability to support them with procedures they are finding difficult.

4.5.2.2 Emotions

This domain relates to specific emotions or feelings which may influence the young person's fear of needles. Important themes in this domain were: fear, anxiety, feelings, and control.

Fear

Fear and anxiety are generally accepted as describing distinctly different emotional states. Barlow described fear as a reaction relative to an immediate and present threat (Barlow, 2000), and in this way some young people described having negative feelings when attending for their procedure, rather than beforehand.

"Just as it's happening in the moment that I expect, you know how you are but when it's happened, I'm a bit like shocked"

Lia, 12yo female

"I'd get really nervous but not really like when it's building up to it, it'll more just be like at the time"

Clara, 13yo female

“You get that feeling that you really don’t want to do, like you say, ‘okay I’ll do it’, and then when you’re about to do it you’re like ‘Oh, I really don’t want to do this”

Batman, 11yo male

This highlights that some young people may not be worried about treatment prior to attending their appointments. It is also possible that some are simply more able to control or suppress their emotions beforehand. In both scenarios, these young people may not be identified as having concerns, meaning others could underestimate their worries or fail to recognise that they may require support.

Anxiety

In contrast to fear, Barlow described anxiety as focusing largely on anticipated or potential threats rather than those which were real and immediate (Barlow, 2000), and in this way some young people described anticipatory negative feelings about their procedure in the time leading up to their appointment.

“I had it locked in my head ever since I got it [appointment]. I was like, I was like counting down the week. I was like, alright three weeks, two weeks, five days, three days, one day. Oh my god, like two hours”

Ryan, 12yo male

‘I get really nervous when I know I’m gonna get a needle”

Emily, 15yo female

Some young people also described how their anxiety would trigger other negative emotions.

“I get worried a bit sometimes and it kind of just sets off all my worries and I just feel really bad”

Chris, 11yo female

This area of discussion highlights that some young people may be worried about treatment in the time prior to attending their appointments. These young people are more likely to be identified by adults and to be offered appropriate support if they are showing outward signs. Some young people may be adept at hiding their feelings, or in controlling them to an extent meaning they may also have their worries underestimated.

Feelings

Young people and parents shared additional feelings associated with needle fear including frustration, annoyance and worries about the future.

Some participants discussed feelings of frustration with their procedure, or with adults trying to help them.

“You sensed my frustration I think because I was going ‘come on right, let’s just try and get it done, you need to sit still’. I probably wasn’t very kind by the end of it”

“So frustrated we didn’t even get an iced coffee, did we? We went home”

Miranda’s mother

“You marched me home in disgrace”

Miranda, 12yo female

“It’s almost annoying when they go ‘oh you’ll be fine, you’ll be fine’. It just makes me feel a bit like ‘I know, you don’t have to go on telling me”

Batman, 11yo male

Other participants also shared their feelings about the consequences of their needle fear, and how this might affect them in the future.

“I’m kind of concerned what would happen in the future because I have been putting off taking it out [tooth], and then it came to the time when it would be best to take it out, and then I, if I wasn’t ready, I don’t know what I’d do”

Chris, 11yo female

“When I get older like I won’t be able to like go on happy gas and stuff all the time so it will like stop me from getting all the treatments I need, erm to stop me having pain and stuff like that”

Emily, 15yo female

“I’m getting worried about not being able to have my teeth pulled out [for orthodontic treatment] because if I can’t have a blood test then I’ll never be able to do that”

Miranda, 12yo female

“It’s caused a delay to your treatment but I think the fear of the needles is again making it hard for you to think about that.....what I worry about more is the here and now, about the short term future, about getting medical interventions done”

Chris’ Father

Sharing worries about the future suggests that needle fear has an even wider effect on the feelings of young people and parents than previously thought.

Control

Young people described their feelings around control and autonomy, including their perceptions of loss of control.

“When I’m actually there I don’t do anything cause I feel like I can’t”

Emily, 15yo female

“They don’t say you can have a choice if you want to look at it or look away. You can do either, it’s your choice”

Batman, 11yo male

Young people also wanted to feel in control, often through being well informed.

“Sometimes like if you’re just getting a needle in you and you don’t really know what it’s for, then I don’t think that’s very good”

Batman, 11yo male

“Just started pulling out a random kind of needle. I felt really, really anxious, I can’t lie, because I don’t know what it does, so yeah I want to know beforehand what it does and how it feels”

Lia, 12yo female

“I think it’s important that the person getting the injection should know what they’re having”

Clara, 13yo female

Young people generally felt a lack of control or autonomy, and that this was being imposed on them by adults through failure to support and offer choice and sufficient information.

4.5.2.3 Behaviours

This domain relates to actions or behaviours which may result from or be related to fear of needles. Within this domain, the main themes identified were coping, avoiding and motivation.

Coping behaviour

Young people and parents discussed some techniques they had tried to help them manage treatment including distractions, breathing exercises and physical relief. Some of these were undertaken by young people themselves, others had input from parents.

“I like look out the window and try and distract myself”

Ryan, 12yo male

“I was just dreaming, I was basically daydreaming on stuff that I really like, like superheroes”

Batman, 11yo male

“In terms of like fidget toys, one of my friends has some and she says that it really helps”

Chris, 11yo female

“I take deep breaths, erm make sure that I keep my breathing calm”

Emily, 15yo female

“I just did something while doing it, I just bit down on some cloth”

Batman, 11yo male

“I held Mum’s hand, and I squeezed it really hard”

Ryan, 12yo male

There were a variety of different techniques discussed in the interviews, highlighting that young people have different preferences and needs from a coping strategy.

Avoidance behaviour

Some young people described some actions they had undertaken or attempted to avoid having a NBP including delaying the procedure or being uncooperative.

Delaying the procedure

Some young people attempted to delay their procedure. This was achieved in different ways such as choosing to monitor a condition instead of treating, trying to miss their appointment meaning it would be rescheduled, or attempting to negotiate with their parent.

“Some treatment that I might need for my tooth I’ve kind of been putting off”

Chris, 11yo female

“I’ve tried delaying it a bit, but it doesn’t work”

Emily, 15yo female

“I try and take the day off”

Mina, 14yo male

“Normally I’ll just try to sleep in the most I can, stay up late, and I just won’t go”

Tigger, 11yo female

“I’ve tried talking my parents out of it but it didn’t work”

Emily, 15yo female

Being uncooperative

Some young people described behaving in such a way that the healthcare professional could not complete the procedure such as moving around or making the procedure unsafe.

“I wouldn’t sit still so he couldn’t do it, because I was panicking, and then I just wouldn’t like keep my mouth open”

Emily, 15yo female

“They were trying to give me a needle and I bit him. And last time when they mentioned putting braces in or giving me a needle or anything about it I just hissed at him”

Tigger, 11yo female

This highlights that some young people who find procedures difficult may take control through refusing or avoiding the procedure altogether.

Motivations

Some young people shared that their behaviour could be guided by their personal motivations, including health or perceived benefit. Where motivation was high, the young person felt they were more likely to accept the treatment.

Health benefits included understanding the need for treatment or the benefit of the procedure.

“I realised that like if I don’t take it my swelling might not die down for a while and I might not be able to breathe. So that kind of scared me into using the needle”

Batman, 11yo male

“If it was a COVID vaccine then I won’t go because like I don’t mind if I get COVID. It’s better than having a needle I’d say”

Rosie, 11yo female

“It was something that I really really wanted to have done”

Miranda, 12yo female

The young people all related to personal, or internal motivations, being important to them. These young people seemed more able to accept care where they were motivated to do so. This suggests that it is important to ensure young people understand *why* they need treatment, and what the direct benefits are, to help them manage treatment successfully.

4.5.2.4 Physical symptoms

This domain relates to physical feelings that young people may experience or anticipate related to needles and needle fear. The main factors identified were: physical manifestations, anticipated sensations and experienced sensations.

Physical manifestations of fear and anxiety

Young people described physical feelings such as sweating, nausea or swirling in their stomach or shaking which accompanied their worries about needles.

“I get sweaty palms and I like; I’ll clench my fist’

Ryan, 12yo male

“I shake a lot and just, I get really stressed out and hyperventilate”

Chris, 11yo female

“I get like butterflies in my stomach, erm, and my leg does shake when I do get nervous a little bit”

Emily, 15yo female

“I felt a bit sick”

Mina, 15yo male

These symptoms are in keeping with those known to occur because of fear and anxiety and can be a good indicator for young people to identify when they are becoming worried.

Anticipation of sensations related to procedure

Some young people spoke of their anticipatory worry about pain during or after their treatment.

“I always thought it was like leave a pain that wouldn’t go away, but it does go away after like maybe an hour”

Batman, 11yo male

“It’s actually going to have to break through the skin and go into like my mouth, and then come back out and I can feel all of that, which isn’t very nice”

Ryan, 12yo male

“I just worry about it like hurting, and I just don’t, I really don’t like the feeling of anything like going in a needle in my arm or in my mouth”

Clara, 14yo female

This highlights that young people have a specific worry about procedures being painful.

Procedural-related sensations

Young people also described previous experiences of negative sensations associated with their procedures including pain, numbness (unrelated to anaesthetic administration), and the sensation of the treatment needle moving underneath their skin.

“When it goes in you can feel it come in, and then you can feel it coming out as well and you can like feel it being in there as well, like a stinging pain”

Ryan, 12yo male

“It just reminds me of like the feeling of having a really numb arm I guess, if I see a needle”

Leon, 15yo male

“It’s the feeling when they’re putting it, when they’re actually taking the blood out, it does it and that’s it, but I feel like when you’re like moving the needle around to find the right place, I don’t like that”

Lia, 12yo female

“I don’t like the pain or anything after it or the feeling of needles going in your arm”

Emily, 15yo female

This highlights that negative physical sensations can play an important role in needle fear. Young people are likely to worry about procedures being painful, leading to anticipatory worry. Some young people have had unpleasant physical experiences during treatment, which may contribute to either worsening or maintenance of their needle fear.

4.5.2.5 Thoughts

This domain relates to the thoughts that young people have which influence their worries about needles. Within this domain, the main themes identified were unwanted thoughts, negative assumptions, and positive thoughts.

Unwanted thoughts

Young people described patterns of negative unwanted thoughts which they considered pivotal to their needle fear, particularly a pattern of thinking whereby they were unable to control this once it had begun.

“When I have something on my mind it’s very hard to like, um, stop me thinking about that kind of thing cause I have this thing like what if but what if but what if”

Chris, 11yo female

“Probably if Mum said, ‘Oh you’re going to have an injection’, like that’s the only thing I could think about for the entire day”

Batman, 11yo male

“It didn’t really hurt, but I think like my brain is thinking that it does hurt because I can see it happening and I just don’t like it”

Clara, 13yo female

“The minute anything goes near her mouth, or in her mouth, that’s it because even if it’s a glove or one of those little mirrors it’s literally that ain’t gonna happen because it could be a needle”

Emily’s Father

This theme highlights that unwanted thoughts can be difficult to control and can contribute to worrying about needles, likely leading to the emotional, physical, and behavioural impacts. Therefore, helping young people to break this cycle of thinking could be instrumental in helping them manage their fear of needles.

Negative assumptions

Some young people shared negative assumptions that they held about treatment, such as things having a bad taste or that several procedures would be worse than a single treatment.

“I just thought it was going to stay there and then when they take it out it’d like leak out or something in my mouth and taste awful”

Ryan, 12yo male

“I was getting really nervous because it was three and like more than one, I just thought, oh I don’t know, I didn’t really like it”

Clara, 13yo female

Positive thoughts

Less young people were able to share positive thoughts that they had, or tried to employ, to help them feel better about having NBPs.

“I just like think it’s going to be in and out and then it’s over and I can go and it’s done and I don’t have to worry about it anymore”

Ryan, 12yo male

This highlights that young people may find it difficult to initiate positive thoughts related to NBPs, either to prevent or stop unwanted negative thoughts.

Following this description of themes attributed directly to the domains of the Five Areas model, the next section will describe preparation, which crosses several domains.

4.5.2.6 Preparation

In keeping with findings in other domains, young people identified preparation as an important factor which could influence their emotions and feelings about needles, as well as helping control their thoughts. There were aspects of preparedness which young people described as supporting them with treatment, while contrarily a lack of preparation or confronting the unexpected was described as unsupportive.

Preparedness

Some young people and parents spoke of instances where an ability to prepare, or having their healthcare professional prepare them, was helpful in managing treatment.

“It’s better that I know because then I can, I can be like right I’m going to the dentist tomorrow and it’s all going to be alright”

Ryan, 12yo male

“Describe how it feels because you prepare yourself for that feeling I think”

Lia, 12yo female

Conversely other young people spoke of instances where an inability to prepare was unhelpful.

“I felt really, really, anxious I can’t like because I don’t know what it does, so yeah I want to know beforehand what it does and how it feels”

Lia, 12yo female

This highlights that for some young people, preparation may be supportive for them when they require an NBP.

4.5.3 Summary

It is clear from undertaking these interviews that some young people are negatively affected by their fear of needles and can find it difficult to accept care in certain situations. In many cases, young people may not have developed effective coping strategies to support them in accepting treatment.

To provide this target population with effective and contextually appropriate support, it was also important to understand their needs and preferences around the self-help resource proposed to help them.

The second part of the interviews was therefore designed to focus on exploring this with young people and parents.

4.6 Resource

Prior to commencing the interviews, it was determined that the resource to be developed would be self-help in nature, to support early access to care, and the provision of support at home. It was also determined that the resource would be based on the principles of CBT based on the evidence for the technique suggesting that this model would be beneficial.

Interviewees indicated that they would like a section for young people, and a section for parents/carers within the developed resource, and therefore the results are separated to demonstrate this.

4.6.1 Preferences for child resource

Within the preferences for the self-help resource, young people and parents discussed how they would like to access the resource, its content, presentation and design, customisation, and privacy.

4.6.1.1 Accessing the resource

Young people and parents shared their preferences for how the resource should be accessed, with young people predominantly suggesting an online resource.

Young people felt that an online resource would make the information more accessible and ecologically friendly although some preferred hard copies for personal use, or to enable those without internet access to benefit.

“I think a website would be good because then you’d know that like everyone can access it”

Clara, 13yo female

“If I was looking at something for information, I would probably prefer it to be online because if I was like looking for something and then I thought of like another question I could type it in like 5 seconds”

Ryan, 12yo male

“It’d be better on the computer because it’s less wasteful, because I feel like with the leaflets you have it at one time, you read it only once or twice and then you leave it to the side always, so I think online would be better because, and if it’s physical you put it in one place and you can lose it. Whereas, if it’s online you just need to google it and it’s there’

Lia, 12yo female

“Yeah, I think all of it should be [printable] because maybe there’s something that someone really needed, and it could get missed out”

Clara, 13yo female

This suggested that an online resource with printable elements may be the best option to address everyone’s needs.

4.6.1.2 Content of the resource

Young people strongly suggested that the content of the resource should include information about needles and NBP including highlighting how common needle fear is, why needles are necessary and what to expect during procedures.

“Yes, actually I would say that like half the children our age, because then it’s like well everyone’s...it’s not just me”

Batman, 11yo male

“What needles and why they’re important and maybe just trying to explain that they’re trying to help you with this, it’s nothing to like be scared about”

Chris, 11yo female

“How it’s going to help you as a person, or like in your body, cause like I just think of a vaccine as like it’s going in and then it comes out and I feel it. But if I’m thinking that it’s going to go in and this could save my life somewhere in the future, then I’m not going to think of it as a bad thing”

Ryan, 11yo male

Children also wanted examples of things that could help them feel better before or during their procedures, and a way to communicate their feelings and preferences to their healthcare professionals.

“Thing having examples of what you can do to distract yourself or take your mind off it would be really good”

Lia, 12yo female

“Maybe things how to like keep yourself calm when you’re there so like you can remember it”

Clara, 13yo female

“Like an information card or something that you could write up and say like ‘Oh I’m scared of this, I’m scared of that, and I don’t really want to do this, and can you help me with this?’”

Batman, 11yo male

When young people were asked how a communication tool might work in practice, they suggested that being able to show it on their phone would be helpful and that it was important to them that the tool was private.

‘I probably show it on my phone to other people...don’t. So, my friends don’t see it. So other people like don’t get made fun of.’

Mina, 15yo male

‘Print it out you could pull that in, you can bring it really close’

Lia, 12yo female

‘I think it would be best if it was customisable and personal for your own business and your own life’

Chris, 11yo female

This suggested several sections that could be included within the resource and should be the primary focus for content.

4.6.1.3 Presentation and design

Young people felt that the resource should be split into different sections, depending on the type of procedure and whether they wanted to access certain information.

“That would like have like different parts that you can like click on, or like snap on”

Ryan, 11yo male

“Maybe say if like they were having something in their mouth they’d find something that would just be for the people getting it done with the arm, it might be very different and they might get a bit confused”

Clara, 13yo female

Pastel or neutral colour schemes were most frequently suggested as appropriate, with blue being a popular choice.

“Pastel colours always work, mostly greens, pastel blues, they are kind of calming”
Lia’s Mother

“I love to have like a dark purple mixed into a dark blue to make like a galaxy look”
Tigger, 11yo female

“I think maybe like neutral colours and like blues and like them sorts of colours as well”
Clara, 13yo female

“Blue, like darker colours than the bright ones, like dark navy blue”
Batman, 11yo male

Finally, young people were asked how they would like information within the resource to be presented. Many preferred graphic to written information.

“I probably would prefer like a graphic, because if it was real people and then I saw like a tooth extraction, and they pulled it out and then I saw like the blood, it would put me off”
Ryan, 11yo male

“Instead of having real pictures it would be much better if it was illustrations, um, it’s a lot less daunting, um, being illustrated”
Chris, 11yo female

This feedback helped to broadly define appropriate colour palettes for the resource and imagery. Furthermore, there was a clear steer that visual information should be prepared to complement written elements.

4.6.1.4 Customisation

Children wanted to be able to customise their experience when using any resources, so that they could select which aspects to engage with or avoid.

“If someone asks, what does it look like, do they have it, but maybe if someone doesn’t really ask maybe it shouldn’t be shown because some people might find it a bit disturbing. I think it would be best if it was customisable, personal for your own business and your own life and that kind of stuff”

Chris, 11yo female

“Written for me”

Mina, 15yo male

This highlighted that young people would have different needs and aims when using the resource and that they need choice regarding what they want to access or avoid.

4.6.1.5 Privacy

Some children raised the issue of privacy, in relation to the resource not being obvious to others.

“They would ask it about it and why I’ve got it and then I like obviously have to explain it all and that I don’t like needles and stuff”

Emily, 15yo female

“I think that it wouldn’t be nice if the person that’s looking suddenly questions you about an app you had, so I think it would be better if it was more for you like something only you know what it’s about”

Chris, 11yo female

This highlighted that the resource design should not be such that it would stand out to other people, or for the content to be immediately obvious.

4.6.2 Parent resource

Parents identified that they felt that they and other parents would benefit from having a portion of the resource targeted for them.

“It would be really good to make sure that children don’t feel that they’re on their own, and that their Mum and Dad have got some learning too to help them”

Chris’ Father

“I honestly as a parent struggled to know what to do for the best”

Miranda’s Mother

“They need to support their child with it, so not projecting their insecurities or fears on the child is very important. So, I think they having a small ‘how to behave in this certain situation’ or ‘how to support your child or a young person’ that is always helpful”

Lia’s Mother

“I think it’s always good to tell the parent information because you don’t always, like you say you have different ways of looking at things”

Leon’s Mother

4.6.2.1 Accessing the parent resource

Children and parents shared their preferences for how the parent resource should be accessed, with both feeling that the parent material should be somehow separated from the children’s resource. There was mixed preference for an electronic or hard copy of the resource but acknowledgement that having both would provide additional access benefits.

“Something that’s just for themselves”

Chris, 11yo female

“You’d like your own information wouldn’t you really”

Leon’s Mother

“Maybe a separate thing with ideas for Mums and Dads”

Lia’s Mother

“I would look on Google or anything to see if I could find something for her”

Emily’s Father

“I like the physical element, physically having something to read”

Emily’s Mother

“Think if it’s an online tool and, for example if it’s a blood phlebotomy clinic, the reception can print out your leaflets and this could be available for people to read, but yeah an online tool”

Lia’s Mother

4.6.1.2 Content of the parent resource

Parents felt the parent resource should contain different kinds of information to the child's resource, including information about how to approach managing their own child's fear.

"That you don't need to hide it from the child that they will have to have the procedure, you probably just be open and talk about it"

Lia's Mother

"From a parent's point of view you know, understanding how to approach them to talk about it is the best way"

Emily's Mother

4.7 Discussion

This stage of the study involved asking young people directly about their fear of needles and is the first to ask them directly about their experiences and preferences for a self-help resource aimed at reducing needle fear. Young people shared many aspects of their experiences, some of which are in keeping with other studies looking at procedural anxieties in this age group.

The Five Areas Model was used as the basis for the topic guide and subsequent analysis of the interviews. This led to early categorisation of some data, as questions were asked based on the five domains, generating deductive data. As very little data was obtained out with the pre-set domains, despite the flexibility of the interview, it seems an appropriate model to apply to studies focusing on anxiety and its impacts. A study on dental anxiety by Porritt and colleagues in 2016 likewise utilised the Five Areas model as a basis for their topic guide and analysis and showed most findings were applicable to one or more domain.

As well as the deductive analysis, an inductive approach was taken, and it was identified that young people also shared thoughts about preparedness which were classed as an additional theme (from the Five Areas) which applied to multiple domains.

Young people described their experiences along the five main areas of the model including what they felt had contributed to the development and maintenance of their fear of needles. They often described unwanted negative thoughts often focusing on fear about pain, or concerns about what would happen during the procedure.

This is in keeping with previously published literature which supports pain as a causative and maintenance factor for needle fear in childhood (Alwafi *et al.*, 2024; Taddio *et al.*, 2022; Noel *et al.*, 2018; McMurtry *et al.*, 2011) and adds to the supportive literature on this topic.

Young people employed a variety of coping mechanisms, some of which had been previously successful, and had multiple ideas for other methods which might be helpful to them, but they had not attempted. Some young people admitted to attempting to delay or avoid treatment altogether by feigning illness, exhausting themselves the night before, refusing to allow access to the area or (in one case) biting the healthcare professional to cause them to remove the item from the child's mouth. Traumatic experiences and subsequent procedural anxiety have also been observed in other paediatric cohorts to impact medical and dental attendance (Ben-Ari *et al.*, 2023; Caleza-Jiminez *et al.*, 2023; Nydell Helkimo, Rolander, and Koch., 2022) This avoidance behaviour could also be interpreted as the young person taking control of their situation. Control, or the feeling of loss of control, is a feature which has been observed in previous papers on childhood needle fear (Noble *et al.*, 2020; Orenius *et al.*, 2018) and has similarly been reported in children with dental anxiety (Morgan *et al* 2017).

Participants also recognised that their relationships with, and the behaviour of, adults could be influential. This seemed particularly relevant for the healthcare professionals providing their care. Young people perceived that healthcare professionals who were empathetic, kind and provided clear information were supportive in relation to their needle fear, while those who rushed them or provided poor or misleading information were unsupportive. The importance of the relationship with, or behaviour of, healthcare professionals in relation to child fear has been reported in some other studies in the published literature (Mahoney, Ayers, and Seddon., 2011) with a previous paper from the same authors and colleagues reporting that staff behaviour does not influence child distress (Mahoney, Ayers, and Seddon., 2010). This suggests further research is needed to clarify the influence of healthcare professionals on childhood fear. Previous work has also alluded to the importance of information provision to young people (Leibring and Anderzen-Carlsson., 2022; Bray, Appleton, and Sharpe., 2019) which suggests that information continues to be an important factor for young people.

Information appears to link to the important concept of preparation, where young people exhibited a preference for being given appropriate information to prepare for their procedures, which may support them in controlling their worries or unwanted thoughts. It is disappointing that some young people felt their healthcare provider was not supporting them, but this may be in part to the lack of specific guidance on discussing healthcare procedures with children.

It may also be due to the different information needs of older children and teenagers compared with younger age groups. Informed consent is gained from parents in many circumstances until young people are competent to consent for themselves (*General Medical Council 2020; General Dental Council 2013*), and perhaps in some situations too much focus is given to ensuring the parent is the person adequately informed.

The most novel finding from these interviews was that young people have long term worries about how their fear of needles might affect them in the future. This is not a theme which has been discussed in the published literature. Young people in this cohort had awareness that their needle fear may interfere with their ability to accept treatment longer term, and that there may be consequences. Many treatment options provided to young people focus only on completing the planned course of treatment. This is not inappropriate, as the treatment is usually necessary to protect health, detect or treat disease or manage injury. These treatment options do not aim to reduce or treat the young person's needle fear and therefore even when they complete their planned procedures, the needle fear can persist. It may not be considered necessary to treat or provide additional support if the person has no further planned procedures. This finding suggests that the needle fear itself has greater impact than simply difficulty tolerating treatment, and young people should be provided with ongoing support or management aimed at reducing their needle fear.

Given the experiences shared by young people during their interviews, it is therefore not surprising that the main request from young people regarding the resource was that it should include information about NBPs. They wanted to understand why they needed NBPs, what would happen at their appointment and how the procedure would feel. Young people also expressed a desire for the resource to contain ideas on how to cope during procedures, and examples of other young people who had overcome their fears and managed treatment. They felt strongly that the resource should be customisable, allowing them to choose what to access depending on their needs. Parents agreed that children would benefit from a resource and expressed a need for some information aimed at them. Specifically, parents felt that advice on how to approach conversations with their child about their anxiety would be beneficial, as well as ideas of how to support their children during procedures. The young people who were interviewed expressed an overwhelmingly clear preference for an electronic resource to help them with NBPs. The parent/carer group had a more mixed desire for electronic or paper-based information. All agreed that a mixed format would be most beneficial. Young people also expressed a desire to communicate with healthcare practitioners providing their care.

Many healthcare resources have been developed over the last five years to support young people with anxiety and fear such as Lumi Nova (BfB Labs), OSCA (Leigh and Clark., 2019), and Silverwell® (Amwell®). Resources specifically for needle fear include Xploro (Bray *et al.*, 2024) Golden Breath (Aydos *et al.*, 2024) and Superkid (Tuncay *et al.*, 2023). There is a growing acknowledgement of the need and benefit of including target end users in the design of development of these resources, which is evidenced by a growing body of literature. Similar studies where children were included in the development of an anxiety resource (and their input was directly reported) shared both similarities and differences to the present study regarding child and parent preferences (Hillet *et al.*, 2022; Porritt *et al.*, 2016).

Porritt and colleagues engaged with young people to develop a guided CBT tool (Your Teeth You Are in Control) for dental anxiety (Porritt *et al.*, 2016). Children and young people involved in developing the resource shared a desire for it to be available in both paper and electronic formats, to include information about procedures and to have an element supporting parents. A communication tool was also developed as part of this project, called Message To Dentist (MTD). There were several aspects of this tool that young people felt would also be beneficial in a tool for communicating about NBPs. The communication tool for this study was developed to address the challenges some young people reported in verbalising their worry to adults. The communication tool MTD is not specifically reported as being developed with the same motivation but appears to have been created to support healthcare professionals in understanding the young person's dental anxiety. Other differences included the request for interactive activities (i.e. activities to complete) as an inclusion in the dental resource, a feature which was not suggested by the needle fear cohort.

Hill and colleagues utilised a user-centred design approach for the development of an online support tool (OSI) facilitating parent-led CBT for children with anxiety (Hill *et al.*, 2022). The key findings from children in the study were that they desired customisability through ability to personalise their game character and wanted to earn rewards. The aspect of customisation, or personalisation, is like the need of young people in the present study to have choice within the needle fear resource. In contrast, young people in the needle fear study did not propose rewards as an important aspect to consider or include. This contrasted with some existing CBT interventions, like OSI and Your Teeth You are In Control, which include specific reference to the use of rewards to encourage positive experiences.

A recently published scoping review which the primary researcher and two supervisors (FS, ZM and GW) contributed to focuses on the preferences of children using electronic health resources to self-manage long term conditions (Court *et al.*, 2024). The review found that children's preferences included some aspects which were seen in this project such as using clear language, customisation and supporting non-verbal interaction. The review also revealed additional preferences including using gamification.

It is reasonable to expect that some of the preferences of young people for electronic and self-help resources will vary over time, as each generation has different needs. Preferences may also differ depending on the nature of the resource or intervention being developed. There are clear preferences across the literature which seem to be globally important, such as the desire for information, clear use of language, resources which facilitate non-verbal communication with healthcare providers, and the ability to tailor and adapt resources to meet individual needs. It is important to continue work with children and young people, drawing on their expert perspective of their own experiences, to ensure that any resources directed at them in future will meet their needs.

This study was based on semi-structured interviews with 13 young people and their parent/carer. A purposive sampling approach was employed, aiming to recruit a range and diversity of experience. During the study it was challenging to recruit, most notably males and children from ethnic minority backgrounds, and these are therefore underrepresented in the participant population.

One of the barriers to the recruitment of some children from an ethnic minority background was the difficulty in communicating during the recruitment process. If an interpreter had not been obtained or had not attended for the child's clinical appointment, it was not possible to adequately discuss the study with the parent. The underrepresentation of non-white British people in research, particularly clinical trials, is a recognised challenge (Premji *et al.*, 2020; Spencer *et al.*, 2022) and a priority for NIHR, who have funded the MERIT (Minority Experiences In Trials) project at the University of Aberdeen to explore specific barriers to recruitment in these populations. It is acknowledged that participants from ethnic minority backgrounds will have different experiences and therefore could have influenced different findings than the children included in this study population.

To try and reduce the effect of this on development of the resource, PPI work was undertaken both formally and informally when designing the resource with young people from ethnic minority backgrounds.

This is described in the next Chapter. Additionally, due to the nature of qualitative research, the findings of this stage can be generalised only to the cohort who were interviewed, and potentially to other young people from the same background in the same geographical area.

4.8 Conclusions

Findings from this line of enquiry with children and parents support the following main conclusions:

1. Children with needle fear describe patterns of unhelpful or catastrophising thoughts
2. Children with needle fear worry about the future impacts their fear may have on their health and wellbeing
3. The Five Areas TM model is an appropriate theoretical framework for the experiences of children with needle fear
4. Healthcare professionals' behaviour is influential in the experiences of children with needle fear
5. A self-help resource would be best hosted electronically
6. A self-help resource should contain information about procedures, information and ideas for coping strategies, a parent section, and a communication tool for use with healthcare professionals

For the purposes of this research, co-design is considered to mean a flexible approach to developing the resource, with the research team working together in partnership with target end service users and key stakeholders. This is based on personal interpretation of the phrases 'co-creation', 'co-design' and 'co-production' as described by multiple published works (Masterson *et al.*, 2022; Nabatchi, Sancino, and Sicilia., 2017; Robert *et al.*, 2015; Verschuer, Brandsen, and Pestoff., 2012; Sanders and Stappers., 2008). The aim of taking this approach is to ensure the development of a resource that truly meets the needs of the target patients (and their families) and is contextually appropriate in multiple settings.

This piece of work would not be considered co-production or co-creation since further work investigating the resource is required prior to considering implementation or future developments.

There are many considerations which were accounted for during the research presented, including ensuring a power balance between the participants and research team as best possible to ensure all felt able to share their personal experiences and views (Thabrew *et al.*, 2018). As the work involved children and young people, additional consideration was given to how they could be effectively engaged within a reasonably short time to avoid burnout. The location for the workshops was chosen deliberately as a non-clinical and non-sponsoring university neutral space, with comfortable settings. The NIHR guidance (2021) on co-producing a research project was consulted at the commencement of the study which lays out five clear underpinning principles required for meaningful involvement of the public in research (figure 5.2). Although this study involves co-design and is not a full co-production project, the principles are still important and applicable due to their overall aim to support meaningful, safe, sustainable involvement of the public. These guidelines were used as a template throughout the co-design process. Taking steps to preserve and provide these kinds of core principles aids in the production of appropriate, effective, and acceptable outputs.

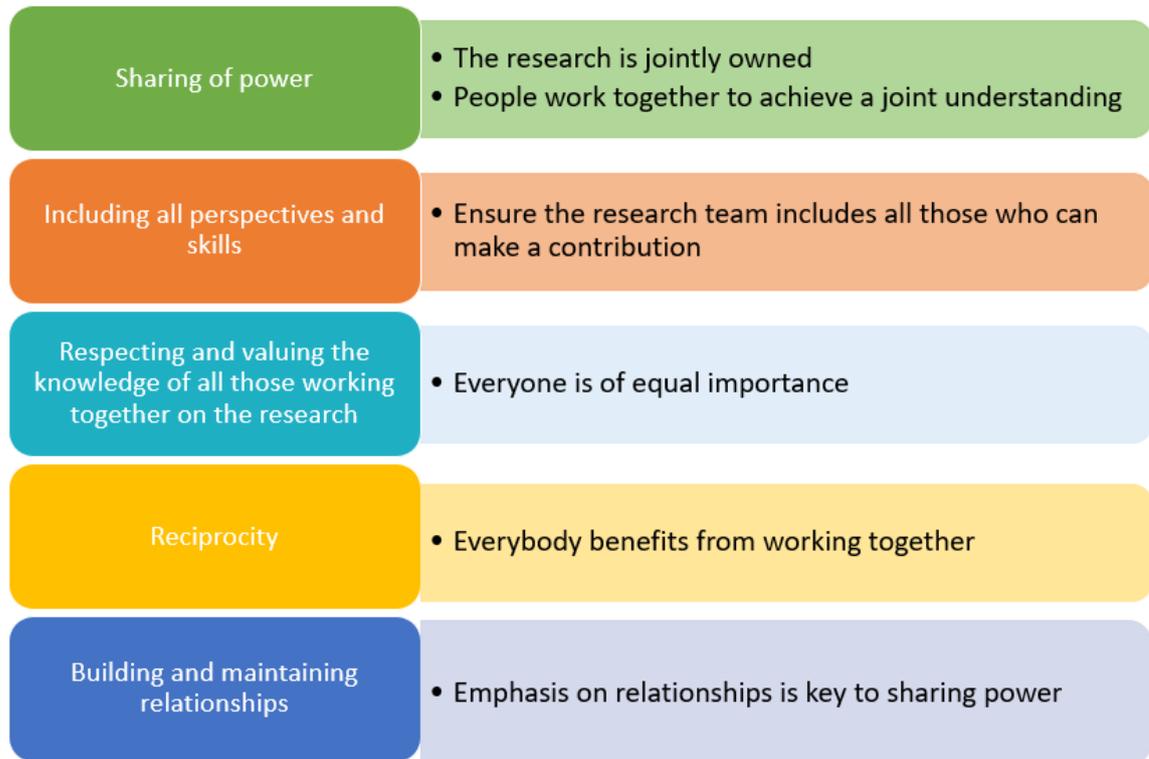


Figure 5.2 Summary of NIHR guidance on co-producing a research project (adapted from NIHR 2021)

5.2 Aims and objectives

The aim and objectives of the co-design process were:

1. To develop a self-help resource to reduce needle fear in children and adolescents
2. To use a co-design approach with children, carers, and healthcare professionals

This would be achieved through:

1. Undertaking workshops with children, parents, and healthcare professionals to design and develop a resource for needle fear based on the principles of CBT and the insights from the Stage One interviews
2. Refining the resource in relation to the needs of children, parents and healthcare professionals and ratify any conflicts
3. Creation of a prototype resource for feasibility testing

5.3 Ethical approval

Ethical approval for this stage of the project was granted by the University of Sheffield Research Ethics Committee (20/09/2023 ref: 052130).

5.4 Method

5.4.1 Initial plan for workshops

The workshops were designed following bespoke co-design training provided by research supervisor GW to FS. This training included shadowing of multiple research projects utilising co-design with both paediatric and adult populations, training in virtual and face-to-face co-design methods, and practical experience of planning and creating co-design activities.

The results from the Stage One interviews, described in Chapter Four, were used to inform the design and content of the workshops, particularly the introductory workshop.

Initially, plans were devised to hold face-to-face workshops for families and healthcare professionals, however during recruitment it became clear that for flexibility, online workshops should also be offered, and the plans were amended (further detail given below).

The workshop aims were pre-defined, but the content and activities were not confirmed until all collaborators had been recruited and preferences confirmed. This was to ensure the workshops met the needs of the co-design collaborators and fitted the setting they had chosen.

5.4.2 Collaborators

Co-design collaborators were children aged 11- to 16-years with needle fear, their parent or carer, and healthcare professionals with patient-facing roles which involved administration of needle-based procedures (NBPs) to children or experience in the management of needle fear. The age range of the children was selected to reflect the target age range for the resource. The collaborators were separate to the core PPI group, who provided insight into the study but did not participate in the study.

Participants were recruited through the public domain. Initially, advertisement posters were shared through X™ (previously Twitter™) and the University of Sheffield volunteer mailing lists with contact details for a member of the research team (FS) who provided written information for the study on request. One poster was created for young people (shown in appendix 10) and another for healthcare professionals (shown in appendix 11). These posters were designed in liaison with the PPI group to help inform both the content and graphics used. As the core PPI group had limited diversity, additional ad hoc input was obtained from medical and dental clinics attended by the lead researcher (FS) to ensure the information was appropriate, and the images used were representative. The core group also contributed to the wording of the patient information sheets and consent forms. Healthcare professionals already known to the research team were approached for interest directly, specifically seeking representation from four different specialties: dentist, anaesthetist, phlebotomist, and school nurses due to their job roles involving the provision of a range of different NBPs to children. Additionally, children and parents/carers who participated in Stage One were informed of the option to participate in this part of the study and were advised to contact FS directly if they were interested. Four participants from Stage One (two children and two parents) contacted FS for further information and agreed to take part.

Initially, recruitment through X™ was poor, with only one HCP responding directly. Through discussion with recruited collaborators, clinical colleagues and the PPI group, it also became clear that face-to-face workshops would be difficult for many people to attend, and this was likely to be a barrier to recruitment. Healthcare professionals also reported that it would be very difficult to arrange a mutually convenient time for workshops when targeting a range of different roles, as working hours varied greatly between disciplines. Considering this feedback, it was decided to offer the workshops for families online to facilitate their attendance. An alternative co-design format was designed for healthcare professionals which would not necessitate them being available at the same time.

Rather than attending workshops at a set date and time, healthcare professionals would be invited to log on to a shared online working space (hosted through the Miro™ platform) at a time that suited them within a given 2-week period. The online workspace would facilitate their review of a set of materials and resources and allow them to leave written feedback, as well as seeing and building on the feedback of other healthcare professionals on the project. The platform would also allow anonymous contributions through the ability to select a pseudonym and use of temporary contact details.

This idea was met with positivity from the healthcare professionals who wished to take part.

The decision was made to replace the term 'workshop' for this group with 'phases' to reflect this more flexible option more accurately. The participant information sheets were amended to reflect that work could be hosted online.

Through further consultation with the PPI group, the original advertising posters (which clearly depicted a face-to-face environment) were edited to reflect online working, approved by the ethics committee, and reshared on Facebook™, Instagram™ and X™ to reach a wider audience. This poster is attached in appendix 12.

Interested parties contacted FS directly, and were sent appropriate written information regarding the study, along with participant information sheet/s. A purposive sample was sought to ensure a wide range of perspectives could be explored (Robinson., 2014). The key characteristics for the young people were gender, age, area-based deprivation, and ethnicity. The classification for ethnicity was taken from the categories used by the Office of National Statistics (ONS) during national surveys. The data for deprivation was taken from the English Indices for Deprivation data from 2019. Children could opt to participate in the workshops with or without their parent/carer also participating in the activities. The key characteristics for HCPs were job role and setting. All collaborators were asked for their preference regarding whether workshops should be held face-to-face or virtually, and for dates and times.

5.4.3 Workshop planning

Prior to the confirmation by the co-design collaborators of their preference regarding workshop location (face-to-face or virtual), planning boards were created. Examples of the boards for workshop and phase 1 are shown in appendices 13 and 14. The planning boards were used to plan the workshop timeline and content to achieve the project aims. One board was created for each workshop or phase, and ideas were added and updated. This allowed the process to be open to participant needs and for changes to be made as we progressed such as adding specific needs, aims and planned activities. The PPI group were consulted throughout, and contributed particularly to ensuring the engagement activities planned were clear, appropriate and feasible face to face and online (once this preference had been identified).

These planning boards were created on the Miro™ platform (www.miro.com), due to the flexibility of being able to adapt the board as time progressed, and for this to be shared with the supervisory team directly.

FS had some familiarity with the tool through her bespoke training with GW and having used it previously with an online PPI group in another project. Information regarding participant needs were added as these were identified.

Initially five young people, five parents and eight healthcare professionals were recruited. One young person and parent requested to take part in a single workshop only, but then withdrew due to home circumstances. One healthcare professional did not participate as they suffered an unexpected bereavement, and one healthcare professional did not respond to communications following consent.

The final co-design group consisted of four young people, four parents and seven healthcare professionals. These are detailed in tables 5.1 and 5.2.

Participant type	Pseudonym	Gender	Age (children only)	IMD
Child	Rosie*	Female	11	6
Parent	Minnie*	Female	N/A	6
Child	Thomas	Male	11	8
Parent	Gertrude	Female	N/A	8
Child	Miranda	Female	13	8
Parent	Patricia	Female	N/A	8
Child	Martha*	Female	14	5
Parent	Maria*	Female	N/A	5

Table 5.1 Family group participants (individuals marked with an Asterix* took part in the stage 1 qualitative interviews)

Job role	Pseudonym	Gender
General Dental Practitioner	Heather	Female
Community Dental Practitioner	Sunshine	Female
Paediatric Support Worker	Lilo	Female
Paediatric Research Nurse	Connie	Female
Paediatric Psychologist	Percy	Male
Paediatric Anaesthetist	Alice	Female

Table 5.2 Healthcare group participants

Adaptations to specific participant needs and preferences

In the family group, one of the children had autism spectrum disorder. Rosie therefore had additional needs that were taken into consideration when planning the workshops. She preferred face-to-face working and requested to have her face-to-face workshops with her mother and one researcher (FS) only. There were no specific needs which influenced the activities undertaken. The remaining three children and parents requested online workshops. Additionally, it was noted that Rosie’s mother worked as a healthcare professional.

In the healthcare professionals’ group, no additional needs were identified at planning stages. All professionals preferred to work in an online phased approach.

For the online workshops and phases, Miro™ was used to host activities. This is due to its flexible nature, familiarity to the facilitators FS and GW, and ability to allow for preservation of anonymity and collaborative working. Individual logins were set for each HCP to protect their email addresses when commenting on the whiteboard.

The family group were sent paper-based activities by post, which they could complete in their own time and then use as a basis for discussion during the virtual workshops. Rosie and her mother were to be provided with these activities during their face-to-face workshops. To support building ideas collaboratively, the comments from the face-to-face workshops were shared with the other family collaborators and vice versa.

The individual workshop and phase contents are described in Section 5.5 below.

5.4.4 Resource planning

Based on the findings from the qualitative interviews, some design guidelines were established to support the co-design process. This included the specification that the final resource was to be accessible online, with downloadable and printable sections. The young people involved also identified a strong preference for illustrations over photographs for images in the resource.

Considering these findings, a few different avenues were explored for hosting the resource. Through consideration of the functionality and discussion with the research and co-design team, a traditional website was selected to allow for quick and easy installation and adaptation of the content and style based on the input from the family and HCP co-design collaborators. This was important to allow prototypes to be shared rapidly with collaborators, and to enable changes to be made as feedback was received.

To develop custom illustrations for the resource, graphic designers working in healthcare were approached. A designer with experience of working on NHS and research resources was selected due to her wealth of experience in communicating with young people and in designing healthcare themed drawings.

The designer was flexible and appreciated the nature of co-design work in confirming the exact number and theme of illustrations.

5.5 Workshops and phases

The workshops and phases were designed for the workshops to precede and inform the phases completed by healthcare professionals. As part of this, a summary of the findings was created at the end of each workshop or phase by the group, to share their thoughts with the other group.

For clarity, the workshops were labelled as 'A' and the phases as 'B' (e.g. 1A and 1B) as shown in table 5.3. The workshops were designed to address specific aims. The activities were designed by FS (with support from GW) with the aim of being familiar to the children and parents, engaging, and supporting them to deliver the aims of the workshops.

The phases were designed to address the same aims, while being complementary to the workshops for the families.

The activities were designed by FS (with support from GW) with the aim of allowing them to engage remotely and support their online contributions.

Workshop	Phase	Aim
1A	1B	Share qualitative findings and introduction to Miro
2A		Seek design and content preferences
	2B	Seek views on information content
OUTCOME - DESIGNER CREATED DRAFT IMAGES		
3A		Develop resource components
	3B	Refine content
OUTCOME - FS DEVELOPED PROTOTYPE WEBSITE		
4A	4B	Review resource

Table 5.3 Workshop and phase aims

5.6 Development of the resource

The prototype resource was developed with guidance from the findings of the qualitative interviews, co-design workshops and phases 2 and 3, and based on the theory of CBT (with input from two psychologists, one of whom is external to the project). A graphic designer (KS) was employed to create illustrations for the resource. The final design and content were confirmed following completion of Workshop 4. The process is described in the sections below.

5.6.1 Prototype resource

5.6.1.1 Workshops and phases

Workshop 1A

Presentation slides were delivered within the Miro™ site which included interactive elements to allow the six online participants to introduce themselves and become familiar with using the site during the workshops.

The same presentation was delivered to the face-to-face participant, and her information was added to the slides in advance of the online session. These can be viewed in appendix 15.

Phase 1A

Video presentations (available on request) were created using Microsoft PowerPoint™ and Quicktime™ where FS explained the project and demonstrated how to interact with the Miro™ website. All HCPs were provided with unique logins to access the Miro™ boards for the study and were asked to access these to introduce themselves to practice using the Miro website and have a chance to troubleshoot any issues with FS prior to the next phases.

Workshop 2A

All families were provided with a postal pack of generative design research activities (as discussed in Section 2.5.3) prior to the workshop which contained: glue sticks, white and coloured A4 card, stickers, washi tape, coloured gel pens, felt tip pens, standard black biro pens and craft scissors. Families were also provided with refreshments in line with what might have been provided in a group face-to-face setting. The pack also contained a variety of different character styles, fonts and colour palettes based on the preferences expressed by participants of the Stage 1 interviews. An example showing the pack contents for workshop 1 is shown in figures 5.3 and 5.4 below. The designer (KS) provided style examples from Adobe Stock to use with the children and young people to help determine how they would like illustrations to be presented and to give ideas for colour schemes.



Figure 5.3 Contents of activity pack delivered to young people and parents



Welcome to your Workshop 2 activity pack Rosie and Minnie!

What's in it?

Inside this envelope you should have:

- ★ A timetable of what will happen at Workshop 2
- ★ Advice for you and your parent/carer about how to use Google Meet
- ★ A separate sheet with information about Workshop 1

If anything is missing or you have any questions, please contact Fiona before the workshop at f.sotir@sheffield.ac.uk.

Who am I meeting?

There will be some other young people and parents there as well as Gemma and Fiona (8 people in total)



Fiona
She is a researcher who will lead the activities and might take notes.



Gemma
She is a designer who will help with the activities and might take notes.

When are we meeting?

Date	Time
19 th October	6.30pm

What activities are we doing?

I would like you to make a Mood board using the pictures in the brown envelope. There are examples of different colours, drawings of people, and different styles of writing. Pick the examples you like best. If you want to, you can make notes about why you like them. I would also like Mum to make a Mood board (or you could make one for them!).

You can make more than one board if you prefer, but one is plenty!

You can be as creative as you like, and when you are finished, please ask your parent to send me a picture of your boards.

What materials will I need?

In your craft bag you should have

- ★ A set of craft scissors
- ★ One glue stick
- ★ One pack of white card (30 sheets)
- ★ One pack of coloured card (15 sheets)
- ★ One pack of felt tip pens
- ★ One pack of coloured gel pens
- ★ One pack of black pens
- ★ One pack of star stickers
- ★ One pack of black and white washi tapes

You can use whatever materials you would like!

I've given you some extra copies of the pictures in case you make a mistake or want to change something.



What will we be doing in the workshop?

1. Introducing ourselves to each other. 

2. Looking at our Mood boards together.

3. Thinking about what our favourite choices are. 

4. Taking a break! 

5. Talking about what information we might like in the resource.

6. Talking about what will happen in the next workshop. 

7. Thanking you! 



Figure 5.4 Activity worksheets and selection of graphics delivered to young people and parents prior to workshop 1A

The collaborators were asked to create mood boards (i.e. a collage of their preferred items from the resources given, with the option to add notes and drawings of their own) prior to the online workshop, based on their preferred images, text and colour.

Each parent and young person completed the activity, with Rosie and Peppa undertaking their workshop first, and all designs then shared at the online workshop, with the chance to discuss and explain their choices. The most popular choices in three categories: font, character and colours were collated, and the group selected their top two favourites in each. Rosie and Peppa were asked to add their votes after the online session. The most popular two design options from each category were then fed back to the designer to act as a basis for her initial character and font designs.

The group were asked if there was anything they would like to share with the HCPs. They requested to share their designs, and specific notes on ensuring the resource was written in simple language, acknowledged the 'normalcy' of needle fear and contained illustrations of a variety of age groups and ethnicities.

Rosie and Gertrude's mood boards are shown in appendix 16.

Phase 2B

All HCPs were provided with examples of existing descriptions of medical and dental procedures for young people taken from existing hospital websites, and some broad ideas of coping techniques for anxiety. Some were taken from the findings of the qualitative interviews, while others were based on the principles of CBT. The family group had also opted to share some comments and examples of their workshop activities with the HCP group.

The collaborators were directed to review the provided examples of procedures and coping strategies. Within the whiteboard, they were asked to consider their own experience and expertise, and to write a paragraph explaining needle-based procedures to a young person which could be included in the resource. They were also asked to comment on the coping strategies, suggest additional options, and to confirm which techniques could or could not be used in their healthcare settings.

The HCPs were also provided with feedback from the family group as per their request and invited to respond or comment. The HCPs positively responded to all comments made by the family group and agreed strongly about inclusivity of images and a diverse population. Concerns were raised about some young people finding any images of needles distressing, and suggestions made to ensure these were optional. No objections or concerns were raised about the design preferences.

The HCPs requested that their responses and concern about images of needles be presented to the family group.

Workshop 3A

The families were provided with examples of existing communication tools used in healthcare, and advice sheets given to the parents of children with dental anxiety and vaccination anxiety. These were provided to give structure to the activity, and to allow the group to utilise or incorporate aspects of the existing resources that they felt were important and/or beneficial.

The young people were asked to design their own communication tool for use during NBPs. As per the findings from the qualitative interviews, they were advised that the tool needed to be small enough to fit on a phone screen or in a pocket. Parents were asked to design a parent information sheet, with advice for adults accompanying children to appointments. The face-to-face workshop was again completed prior to the online session.

At the online workshop, all the designs were discussed between collaborators, and a consensus reached about what should be included in the parent advice section. An example of the returned designs can be seen in appendix 17. One communication tool, designed by Rosie, was the clearly favoured option and the young people agreed that this should form the basis of the design for the resource tool. This design is shown in appendix 18.

Three initial images were created by the designer KS in response to the feedback from workshop 2A – an illustration of a parent, an illustration of a child and an example of title text to demonstrate font style. These were presented for comment on any aspects the group thought could be altered or improved.

The group liked the colours and character style and asked to feed this back to the designer. They commented that they felt the final set of character illustrations should represent a diverse population.

Comments were made suggesting a website with a mobile version and printable elements would be the preferred format.

The group requested to share a sample of their designs with the HCP group (Rosie, Peppa and Gertrude's) along with comments that they also felt some images should be optional viewing.

They also commented that it was important that the communication tool would be used and appreciated by HCPs, and that the language used across the resource should be simple so it could be understood by all (including those with English as a second language, or with reading difficulties).

Phase 3B

All HCPs were provided with the comments from CYP and parents in workshop 3A, examples of existing communication tools used with healthcare professionals and examples of existing parent advice sheets for children with worries about healthcare procedures to use as a basis for comment and feedback.

The designs shared by the families were presented first to allow the HCPs to consider their thoughts based on the preferences and needs of the families.

HCPs were asked to consider the communication tool examples and what information they felt would be helpful to know about young people with needle worries. They were also asked for what advice they might give to the parents of these young people and considered important for inclusion in the resource.

The HCPs were impressed by the designs shared by the family group and felt that Rosie's design for the communication tool was excellent and likely to meet the needs of both the young people and HCPs who might be given it during an appointment.

The draft images which had been created by the graphic designer were also shared. No comments were made for feedback to the designer.

The HCPs asked to feedback their agreement that the resource language should be inclusive to allow it to be understood by a wide range of people.

Website design

A website builder was used to develop the tool, rather than an external company, to allow for more agile, timely amendments to the prototype without introducing additional time and costs. The website builder provided a blank template which could be customised without the need to use code. The website was created and populated by FS.

The Wix website tool (www.wix.com) was selected due to its ease of use, ability to provide a range of layouts, sufficient storage capacity, ability to embed necessary visual and audio content, retain an appropriate uniform resource locator containing the name of the resource and due to FS having previous experience with the website builder. This website builder is free. The website also offered further functionality that may be of benefit in future iterations, including being able to attach an owned domain for reasonably low cost.

Firstly, sections were created based on the preferences and needs identified from the qualitative work and co-design workshops.

The five sections included in this initial version were:

1. Home page
2. Resources for young people
 - a) Why do I feel worried?
 - b) How do I know when I'm worried?
 - c) Types of needle treatment
 - d) How to cope when you need treatment
 - e) Real life story
 - f) Communication tool
 - g) Other resources
3. Resources for parent/carers
 - a) Young people and worries
 - b) How to have conversations
 - c) How to help yourself feel better
 - d) How to help your young person
 - e) Other resources
4. Feedback
5. Contact us web enquiry form

FS discussed with clinical colleagues and the HCP collaborators, which common needle-based procedures should be included in the resource, with reference to the procedures most mentioned by young people in the Stage One interviews and co-design workshops.

An agreement was reached to include vaccinations, blood tests with finger pricking and venepuncture, cannulation for medications or general anaesthetic and intra-oral dental injections as these were a broad range and relatively common for young people in the target age group.

The graphic designer was asked to create 24 stand-alone images to complement this content including: images of the various needles used for treatment; images of worried young people; happy young people and parent/carers. Additionally, illustrated story boards were requested to demonstrate the general process of six different needle-based procedures and one real life story. It was agreed with the family group and PPI group that the real-life story text of a young person using the resource should be written after the study based on a real example.

Written content in sections 2c-g and 3c-f was created based on the input from the co-design group. Content for sections 2a, 2b, 3a and 3b was written by the lead researcher FS who had undertaken an introductory course in Cognitive Behavioural Therapy with overview and input from two paediatric psychologists experienced in the management of young people with specific fears and phobias.

The section on real stories (2e) and feedback (4) were populated with created stories for illustrative purposes, as the resource had not been used and therefore true scenarios and statements could not be used. These would be replaced with real statements from either PPI representatives or co-design collaborators for the purposes of the feasibility study and would then be replaced with real stories when these could be collected.

The lead researcher, FS, learned how to utilise the website builder and created all content herself, from scratch, with the exception of the graphics, which were provided by the graphic designer (KR). This process was time-consuming, and presented a reasonably steep e-learning curve, but was immensely beneficial in being able to directly control the format and design, and for making iterative changes in response to suggestions and feedback from the co-design collaborators, and later from the wider PPI group. It also allowed for the development of technical skills which will be of benefit in future similar projects.

5.6.2 Second prototype resource

5.6.2.1 Workshops and phases

Workshop 4A

The families were provided with access to the resource alongside an activity book, which had reflective questions and activities to help guide and structure feedback (see appendix 19) such as ‘did you understand everything in the parts you chose to look at?’ and ‘if you could change one thing about the resource, what would it be?’. Parents and children were given separate packs to work with, to allow them to record their thoughts and ideas independently but were encouraged to compare and discuss their thoughts with each other afterwards.

The workshop had to be postponed due to the delay in receiving the images from the graphic designer. Unfortunately, the group were not able to identify a further time and date for a joint online workshop together. As an alternative, once they were ready to share their feedback, FS offered to undertake a 1:1 workshop, with each participant/family dyad individually at a time to suit them. Three of the four families requested a final workshop, with one family (Miranda and Patricia) opting to have their packs collected and communicate by email with any questions.

The feedback was generally positive.

Specific changes which were suggested were: addition of audio recordings for lengthier sections, increased font size and reduction in needle size on the illustrations. These suggestions were integrated into the resource.

Phase 4B

The phase had to be postponed due to the delay in receiving the images from the graphic designer. This did not cause any issue in this cohort, who were able to commit to review of the resource in a slightly later time window.

The HCPs were provided with access to the resource alongside an activity book, which had reflective questions and activities to help guide and structure feedback (see appendix 19).

The feedback received was generally positive. Alice, the paediatric anaesthetist, requested a 1:1 meeting to discuss amendments to the section on general anaesthetics. This was due to guidance from the Royal College of Anaesthetists on the language that should be used with young people to describe the process of general anaesthetic.

Based on this guidance alongside Alice’s professional opinion and experience, the suggestion was to remove any reference to ‘going to sleep’ or ‘being put to sleep’ instead substituting ‘having an anaesthetic’. This wording was checked and approved by three child PPI representatives and two co-design collaborators, Thomas, and Rosie. The HCPs had also commented on the length of the illustrated needles, in consensus with the family group.

5.6.2.2 Patient and Public Involvement

In addition to the co-design group, the resource was shared with four of the core child PPI representatives, two core parents and three ad hoc healthcare professionals who had not participated in the project (paediatric nurse, GP, and paediatric rheumatology nurse).

The feedback was positive. Suggestions for improvements were addition of a faces scale option for the communication tool in addition to the present options, addition of a section to cover subcutaneous injections as another reasonably common treatment, increase to font size and future creation of a QR code to enable website to be shared.

As these suggestions involved increasing inclusivity of the resource, they were agreed for addition.

5.6.2.3 Website amendments

In line with the agreed feedback from the co-design group and PPI representatives, the following updates or amendments were made:

- Increase of all text sizes by 2 points (title points from 20 to 22, headings from 18 to 20, main body text from 14 to 16)
- Additional of audio recordings to supplement sections 2a, b, d and 3a, b, c, d
- Removal of all references to ‘going to sleep’ or being ‘put to sleep’ from section 2c
- Revision of images of needles from section 2c to portray a shorter needle length
- Addition of a communication tool with a faces scale option
- Addition of a section about subcutaneous injections
- Creation of a QR code to enable access to the resource

The graphic designer (KS) provided amended images of the needles for sections 2C, with shorter needle points as requested. She had also shown her images to her own child, who is autistic, and had considered that there was no representation of a child with neurodiversity. She provided an additional set of child characters for the website, one with ear defenders and one with a sunflower lanyard, to address this omission. These images were incorporated into the existing design.

5.7 Discussion

This stage of the study involved co-designing the self-help resource with young people, parents, and HCPs. Co-design was identified as an appropriate methodology to ensure that young people could contribute their unique expert perspectives in a supportive environment. It was considered that traditional academic methods, such as interviews, may preserve traditional power dynamics, and favour certain forms of knowledge sharing – especially spoken and written. Co-design can be more inclusive, and therefore supports the inclusion of a whole new cohort of potential collaborators. It also allows for, and places value on, other forms of communication. Adoption of this approach should result in the developed resource being more likely to meet their needs and being more contextually appropriate from an early stage in the process.

For this study, young people were involved in two parts: those participating in the qualitative interviews, and the co-design collaboration.

The findings of Stage One of the study, the qualitative interviews, were used to inform aspects of the co-design process. Where the interviews had indicated a clear preference, or strong suggestion, for aspects relating to the resource, these were incorporated into the engagement activities undertaken by the co-design collaborators, which then informed the development of the website resource. Examples of the preferences and how these were incorporated into the final website are shown in table 5.4 below.

Preference	How was this achieved?	Examples of how this was included on the website
<p>Resource should be hosted online but with printable elements</p>	<p>Collaborators informed this was a non-negotiable aspect of the resource</p> <p>Asked for suggestion of how this could be achieved</p> <p>Asked to beta test the resource as final part of their collaborative workshops or phases</p>	<p>Each page of the website can be downloaded in PDF format</p> <p>This can be saved to a device to use offline or printed to use as paper resource</p>
<p>Content should include information about needle-based procedures</p>	<p>Young people were asked about what information they felt should be included in the resource, and how this information should be presented</p> <p>Young people were asked about the language that should be used (formal names or descriptions)</p> <p>HCPs were asked to contribute to writing the content based on their experience and expertise</p> <p>Both groups were asked to review the final wording and make suggestion for improvements</p>	<p>The website includes sections on common needle-based procedures</p> <p>These are written in appropriate language avoiding jargon</p> <p>The official name for each procedure is included in the information provided</p> <p>Illustration of the needle used are available if young people wish to access this</p> <p>A storyboard of what their procedure might look like is included if young people wish to access this</p>
<p>The colour scheme for the resource should be calming (suggestion of pastel colours, blues, or greens)</p>	<p>These preferences were shared with the graphic designer (KS) who created worksheets for the family group to use in an engagement activity to indicate their style preferences</p>	<p>The final illustrations for the resource are based on a calming blue/green colour scheme</p>

<p>Content should include information on coping strategies</p>	<p>Young people were given examples provided by the qualitative interview participants and asked for further ideas of coping ideas they might use or suggest</p> <p>HCPs were given the examples from both the qualitative and co-design groups and asked to comment whether these strategies would work in their setting, and suggest additional or alternative options</p>	<p>The resource contains a section on coping strategies, separating into different categories</p> <p>Ideas are also suggested based on the procedure the young person will be having</p>
<p>Parents indicated that they would like a section of the resources directed at helping them support their child</p>	<p>Parents were provided examples of existing advice given to the parents of children attending for needle-based procedures</p> <p>An engagement activity was designed to allow parents to design their own ideal advice sheet, incorporating their own ideas with any they found useful from the existing resources</p> <p>HCPs were asked to contribute any advice they give to parents attending for specific procedures</p>	<p>The resource has a separate section for parent or carers</p> <p>This section contains information to help the parent or carer understand needle fear, how to approach discussions, how to help their young person through action and behaviours, and how to support their young person in using a coping strategy</p>

<p>Young people indicated that they would like a communication tool to support non-verbal communication with HCPs.</p> <p>The communication tool should be something which is not obvious to others and/or could be used on a smartphone.</p>	<p>Young people were provided examples of existing communication tools</p> <p>An engagement activity was designed to allow young people to design their own communication tool</p> <p>Young people were advised that the tool had to be small enough to be hidden in a pocket</p> <p>HCPs were asked to comment on the design and suggest any other elements they would find useful to know about a young person attending</p>	<p>A communication tool was designed which can be folded and kept safely in a pocket</p> <p>Three versions were created to allow young people to choose how to measure their worry</p> <p>The tool can also be used and presented on a mobile device</p>
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Table 5.4 How the preferences shared during stage 1 were incorporated into the final design

Working online, or having the researcher attend their home, reduced the travel burden on collaborators and allowed them to work on their activities at their own pace in their own context. All young people and parents completed the activities, which may not have been observed if the workshops or phases were held face-to-face. Collaborators also may have felt more comfortable in their home environment and more able to share their ideas and opinions. There was initial concern that this may hamper the development of rapport between the researchers and collaborators, including between the collaborators themselves. The provision of workshop activity packs by post with refreshments was employed to mitigate this by allowing the young people and parents to meet and chat to the lead researcher (FS) ahead of the workshops and seemed to be effective. Young people, parents and HCPs seemed to work well together, and made comments kindly and constructively. Where there was any disagreement, this was left to the collaborators to discuss and come to a compromise. The research team did not have to step in to manage these minor disagreements but simply facilitated discussions and an outcome was always reached where all participants were happy to move on.

It was important to ensure the resource was also based on the principles of CBT, as per the original aim of the study. Many of the suggestions made by young people and parents in stages one and two were aligned to these principles – such as wanting to understand needle fear and learn coping skills to help them manage their fear. It was determined early in the planning stages of the study, prior to applying for funding, that a paediatric psychologist should be included as a collaborator in the healthcare professional group, to aid in moderating the content with supportive and helpful language and ensuring the suggestions made by both groups were appropriate for the reduction of worry. The advice and input of the psychologist was also sought to ensure the resource was based on and reflective of the principles of CBT. An external paediatric psychologist was also invited to contribute to early review and development of the resource to ensure there was agreement that the resource had a foundation in CBT. The Five Areas Model was selected as the model of CBT for this study, and the resource was loosely mapped to each of these areas, to ensure all aspects were addressed in some way. Both psychologists independently agreed that the final resource, as provided to the collaborators and PPI group in Workshop and Phase 4, had achieved this aim.

During the study it proved challenging to recruit, most notably males and children from ethnic minority backgrounds, older children aged 15-16 and those from the most deprived areas and these are therefore underrepresented in the collaboration. The barriers to recruiting children from these backgrounds are not easy to identify, as the recruitment took place over social media. It may be that for some families, difficulty with written English on the advertising poster could have been a barrier to taking part which may partly explain the lack of diversity in the group. The PPI group also lacked diversity, and therefore the recommendations made for recruitment may not have reflected the needs of different groups. As described in Chapter Four, there is a known challenge with underrepresentation of non-White British residents in research (Spencer *et al.*, 2022; Pemji *et al.*, 2020). It is possible that some families from areas of deprivation do not have reliable access to the internet and would have been unable to see the recruitment poster. They may also not have been interested in the project, or parents may not have been supportive of their child's interest in taking part. It is also possible as co-design is a reasonably new methodology, that they were not familiar with the concept, or did not understand what it might involve.

On reflection the poster does not clarify that there is no cost to taking part, which may also have discouraged some people from seeking further information. It is acknowledged that these young people and families will have different experiences, ideas and needs and therefore their needs may not be directly met by the developed resource.

To mitigate this to a very small extent, both formal and informal PPI input was specifically sought from young people and parents attending hospital clinics from backgrounds not represented in the original collaboration (which was entirely comprised of white collaborators) during the review of the illustrations and prototype resource.

As the resource is electronic, there is also scope to adapt it easily in future, to meet the needs of other populations, and the author is hopeful that further work can be completed in this area.

The co-design collaborators all contributed to the development of the resource by sharing their ideas, thoughts, experience, and with an empathetic consideration of others, to develop a resource which is applicable to children faced with a range of needle-based procedures. The collaborators were thanked for their time with a £20 voucher per workshop or phase.

As per the NIHR guidance (2021) which suggests ongoing reflection from the collaboration, all collaborators were encouraged to share their experiences with FS if they wished. The guidance specifically states under the section 'Continuous reflection' that this should not be confused with supervision, appraisal, or review such as might be provided as part of a job role. As a person requiring formal written feedback is usually one in a position of power (a manager or teacher for example), it was decided that to maintain the more equal balance of power between collaborators, no formal evaluation would be undertaken.

Interestingly, collaborators revealed some additional personal benefits they had gained from their involvement in the project.

Rosie and Peppa expressed gratitude for their involvement and looked forward to seeing the outcome of the project. They had enjoyed spending the time working together during the activities - they did not often spend time alone together. Peppa, a dental therapist, was eager to use the tool with patients and asked to be notified when the resource was 'live'.

Patricia commented that her daughter, Miranda, had benefited greatly from taking part in the project. She advised that Miranda was an anxious teen, and she had gained confidence from undertaking the online sessions and talking about her ideas and thoughts. She was also planning to use the communication tool at her upcoming vaccinations.

The HCPs were impressed by the mood boards, communication tool, and advice sheets which had been created by the family group and commented on the time and effort which had been invested in creating these outputs.

All HCP collaborators privately shared with the lead researcher, FS, that they had enjoyed taking part and felt like their contributions and collaboration had made a real difference. They could see the benefit of a co-design approach and may either take or advocate for this approach in their own future practice.

It seems clear that this co-design collaboration was very successful due to the engagement and input of all its members. The aims of each workshop and phase were easily met through the enthusiasm and commitment of the collaborators to taking part, and the researchers facilitating this stage (FS and GW) were especially heartened to hear about the positive experiences of taking part and of the wider benefits gained by some. A well-considered co-design process, adapted to the specific needs of participants, can therefore lead to better outcomes for the project (as identified in the literature), but can also lead to personal growth and can be an enjoyable experience for the collaborators themselves.

The developed resource is still in a prototype stage, with further adaptation possible. Information about acceptability will be collected as part of the feasibility study, and this may be used to make further improvements in future. This will be discussed in Chapter Six.

5.8 Conclusions

The value of co-design in healthcare research was clearly evidenced through this stage of the project and the following conclusions can be made:

1. Young people can make effective, valuable research contributions when appropriately supported to do so
2. Young people should be supported to contribute to research in non-written formats to encourage those with literacy challenges
3. Co-design can be effective and appropriate method for the development of healthcare resources with the target population
4. Co-design was an appropriate method for the development of this resource
5. The adaptive nature of co-design is beneficial when changes are needed to processes or methods to support collaborators to participate equally and meaningfully (including but not limited to those with communication support needs - particularly those who find written communication challenging)

6. Meaningful co-design that is adaptable to participants' needs can provide additional benefits to collaborators beyond the ability to participate in and contribute to research such as improving their self confidence

Chapter Six

6. Feasibility study

6.1 Introduction

Needle fear is a frequently experienced issue for children and young people with 50% affected worldwide (McLenon and Rogers., 2019). At the commencement of this study, no self-help resource based on the principles of CBT existed to support these young people which had been developed either *with* or *for* young people with needle fear. The first two stages of the study led to the co-design of such a resource, as described in Chapters Four and Five, aimed at young people aged 11 – 16 years old which aims to support young people in accepting treatment and reducing their fear of needles. Presently, there is a paucity of evidence to ascertain if self-help resources are effective in the management of needle fear in young people, and the novel resource is yet to be tested. Provision of support for young people currently varies across the country, with many requiring referrals into primary or secondary care settings to access certain management techniques such as graded exposure, hypnosis, or CBT. In home settings, young people may be able to access some information on coping styles through self- research. This mixed-method feasibility study aims to determine the acceptability of the resource and whether a randomised controlled trial would be an acceptable and feasible approach for a future definitive assessment of this self-help resource. In considering the definition and design of the work, reference was made to the existing literature including Eldridge and colleagues (Eldridge *et al.*, 2016).

6.2 Aims and objectives

The aim and objectives of this stage were:

1. To conduct a feasibility study of a self-help resource to reduce needle fear in children and adolescents to inform a future study

2. To address the following uncertainties
 - a. The most appropriate self-report measure of needle fear (the primary outcome of a future trial)
 - b. The perceptions of key stakeholders (such as phlebotomists, dentists, anaesthetists, research nurses) on the resource and on their willingness to recruit participants
 - c. Feasibility of recruitment
 - d. Retention and completion rates
 - e. The acceptability of the developed resource to children and their parents, and their willingness to be recruited

This would be achieved through:

- The conduction of a feasibility study in three settings (secondary dental care, secondary medical care, and schools)
- The conduction of semi-structured interviews with a subset of participants, parents, and healthcare professionals

6.3 Ethical approval

Ethical approval for this stage of the project was granted by the London - Westminster Research Ethics Committee (01/12/22 ref: 22/PR/1451)

6.4 Method

6.4.1 Study design

An uncontrolled feasibility study was undertaken. The study was not randomised as this would increase the time and resources required, without providing additional beneficial evidence as acceptability and implementation of randomisation are not a concern. Therefore, all participants were given access to the resource during the study. This Chapter was written with reference to the guidelines for reporting non-randomised pilot and feasibility studies (Lancaster and Thabrane., 2019) and the Consolidated Criteria for Reporting Qualitative Research Checklist (Tong *et al.*, 2007).

6.4.2 Participants

6.4.2a *Quantitative element*

Eligible participants were children aged 11-16 years with needle fear, and a planned needle-based procedure (NBP). Presence or absence of needle fear was determined through a screening question (as with stage 1 of the study). The screening question was 'how do you feel when you need to have a needle?'. Young people could choose from four options: very worried, a little bit worried, not at all worried or would rather not say. Young people choosing either 'very' or 'a little bit' worried were eligible for inclusion. Young people were excluded if they did not fit the age criteria, did not have needle fear, did not have a planned NBP or did not have the capacity to assent to participate. This age range was selected to match the target age range for the developed resource. Three settings were selected for recruitment: a children's hospital, dental hospital, and schools. The children's hospital setting would include different clinics where young people might attend for NBPs, the dental hospital setting would include paediatric dental clinics and the schools would include young people due to have a planned HPV vaccination.

Participants in the healthcare settings were approached directly by a clinician involved in their care or research trained clinician (FS) at their scheduled appointment. They were given verbal information about the nature and purpose of the study and the child, and their parent/carer were provided with written information sheets. Consent and assent forms were provided and were either completed at the initial or subsequent visit.

The school cohort were introduced to the study by FS and a trained research nurse (KP) during an assembly about their upcoming vaccinations. All children were provided with a research pack which included written information for the children and their parent/carer, consent and assent forms, screening question and baseline questionnaire and contact details for the research team. Children who wished to participate were asked to complete the paperwork and return this to the school office. Consent was sought to contact the participants to inform them via email if they had met the eligibility criteria.

A target of 60 participants with 20 participants from each setting was set for this element, considered sufficient to assess feasibility in each and to measure the variability of candidate outcome measures with reasonable precision. It also allowed for an adequately sized, heterogeneous, purposive qualitative sub-sample to be recruited for the interviews.

It is in keeping both with the median target sample size for feasibility studies undertaken in the UK (Billingham, Whitehead, and Julious., 2013), and generally recommended sample sizes (Teare *et al.*, 2014; Sim and Lewis., 2012).

Post hoc amendment

A post hoc alteration was made to the original protocol for school settings, to include a wider geographical area (expanding from Sheffield to include schools within South Yorkshire) and to remove the need for the planned vaccination to be HPV specifically. This was due to a low response rate from schools in the Sheffield area and to allow for greater flexibility in timing as the HPV schedule varied greatly between schools.

6.4.2b *Qualitative element*

Child interviews

Participants were children who had completed all activities in the quantitative element of the study, plus their parent or carer. Of the children and parents from the quantitative feasibility element who consented to be contacted, a purposive sample of 20 children were invited to undertake follow-up interview. A sampling matrix was used to seek a wide range of perspectives. Key characteristics included: gender, age, setting, area-base deprivation, ethnicity, whether the child completed their planned NBP and whether the child did or did not engage with the resource (if this was known). Recruitment would be continued until no new information was gained.

Healthcare Professionals

Participants were professionals who had either administered a NBP to a child who received the self-help resource or who had been involved with recruitment. A purposive sampling matrix was used to ensure a wide range of perspectives. Key characteristics included: job role, setting, and role in the study. Recruitment would be continued until no new information was gained.

6.4.3 Data collection

6.4.3.1 Settings and sites

The settings which were proposed for inclusion in the study were:

- A children's hospital
- Specialist paediatric dentistry clinics within a dental hospital and satellite community dentistry clinics
- Public secondary schools

The hospital settings were directly approached by the primary researcher. Within the school setting, all secondary schools in South Yorkshire were approached except for those deemed 'inadequate' at their last Ofsted inspection. This was deemed appropriate as these schools have been assessed as not providing an acceptable quality of care and education, meaning they must take steps to make significant improvements. It was felt that the priority for these schools was to improve the education quality rather than participate in external projects, and the research team did not wish to disrupt this process.

Data on schools in the region was taken from local council webpages. Emails were to be sent to the Headteacher of each school directly where contact details were available, or through the school contact email. These included a cover letter explaining the study, which can be viewed in appendix 20. One follow-up invite was sent in the absence of any response to the initial email.

6.4.3.2 Quantitative element

Baseline questionnaires were completed by the children immediately following the consent process to capture basic demographics (gender and ethnicity), nature of any previous NBP and a baseline score of needle fear on the three candidate self-reported outcome measures (VAS, CFS and IPS-Anx-C).

The VAS is a single item question which measures an attitude or characteristic over a continuum of values. It is comprised of a 100mm line with descriptors at either end. The scale is described in more detail in Section 2.4.1. The question used in this part of the study was 'how do you feel when you need to have a needle', as previously defined by the PPI group, with the 0mm point showing 'not at all worried' and the 100mm point showing 'extremely worried'.

The CFS is a single item measure which measures needle fear specifically. It is comprised of five sex-neutral faces, scored from 0 – 4, commencing with a neutral expression (0) which gradually becomes more concerned (4). The scale is described in more detail in Section 2.4.1. The question used in this part of the study was ‘how do you feel when you need to have a needle’, as previously defined by the PPI group.

The IPS-Anx-C is an 18-item questionnaire, with each question graded along a five-point Likert scale. It has been adapted from an adult measure, but with more child friendly language. The scale contains questions related to different aspects of needle and hospital-based experiences. The scale is described in more detail in Section 2.4.1

Children and parents were subsequently directed to the resource on the same day by the primary researcher FS.

The children recruited from healthcare settings were offered access to the resource via email, text or QR code. All parents opted to have the resource forwarded to them by email. Children were then asked to complete a second record of needle fear on the same outcome measures at their treatment appointment, before they were called in to have their NBP. The baseline and follow-up questionnaires can be seen in appendices 21 and 22.

The children recruited from school settings were all forwarded the resource access by email. Children were subsequently sent an electronic questionnaire 2 days prior to the planned vaccination as there was no way to provide them with a paper-based copy while maintaining their anonymity as study participants.

All participants who completed the study activity were provided with a £10 gift voucher to thank them for their time.

6.4.3.3 Qualitative element

Young people and parent/carer

Semi-structured interviews were conducted with participants over a five-month period. The interviews ran concurrently with the quantitative element and were undertaken by a lone female researcher (FS). Her background is described in Section 4.1.1 above. A PPI group, consisting of young people aged 11-16 years old and parent representatives was consulted and aided in the creation of participant information sheets and consent forms for both young people and parents.

Only participants who had given consent to be contacted were invited to participate, and the study information was sent electronically. As with Stage One, participants were given the option to undertake their interview face to face, via telephone or online. For those who opted for face-to-face, they were given the choice of the interview taking place at their clinic, at a venue within the University of Sheffield, or in another appropriate venue of their choice – such as their own home. Face-to-face participants were provided with refreshments and offered reimbursement of reasonable travel expenses. Interviews were conducted by a lone female researcher (FS). A topic guide was developed by FS to support the interviews, using the Five Areas Model of CBT as a guide (Williams and Garland., 2002). The topic guides are attached in appendices 23 and 24. The topic guides were modified following review by the supervising researchers (ZM, HR and DW) and input from the core PPI panel. The topic guides were used within the interviews to stimulate and guide conversation, with scope for exploration of additional ideas which emerged. Supportive materials such as arts, crafts and whiteboards were offered to complement verbal interviews and help children express their thoughts, as some children are known to find them difficult to verbalise (Clark., 2005).

Healthcare professionals

Semi-structured interviews with healthcare professionals were conducted over a 5-month period. The interviews ran concurrently with the quantitative element and were completed by a lone female researcher (FS). Ad-hoc PPI input was sought from healthcare professionals in the creation of the consent forms and participant information sheets. As with Stage One, participants were given the option to undertake their interview face-to-face via telephone or online. For those who opted for face-to-face, they were given the choice of the interview taking place at their workplace, at a venue within the University of Sheffield, or in another appropriate venue of their choice – such as their own home. Participants were also offered the option of completing individual or group interviews. All participants opted for face-to-face interviews at their workplace. From the children's hospital setting, the participants requested to attend for a group interview. Participants from other settings requested individual interviews. Participants were provided with refreshments and offered reimbursement of reasonable travel expenses. Interviews were conducted by a lone female researcher (FS). A topic guide was developed to support the interviews, based on a similar study undertaken with healthcare professionals working with dentally anxious children (Morgan *et al.*, 2017). The topic guides are attached in appendices 25 and 26. The topic guide was developed and modified following review by the supervising researchers (ZM, HR and DW). The topic guide was used within the interviews to stimulate and guide conversation, with scope for exploration of additional ideas which emerged.

At completion of their interview, all participants were provided with a £10 gift voucher to thank them for their time. The interviews were audio-recorded and transcribed verbatim by a professional external company Dictate2Us (Manchester UK). Personal details were removed prior to transcription, with pseudonyms used during the interviews. Participants were recruited until no new ideas were identified, or until the participant pool was exhausted.

6.4.4 Outcome measures

The following outcome measures were used to address the aims and objectives stated in Section 6.2.

- Recruitment rate measured as the ratio of invited vs accepted settings and participants
 - Consideration of available population and estimation of numbers needed in future trial
- Completion measured as proportion of those who completed all measures
- Completion of candidate primary outcome measures and missing data rates, standard deviation of outcome measures and comparison and analysis of qualitative interviews to determine most appropriate self-report measure of needle fear.
- Analysis of qualitative interviews to explore
 - Perception of key stakeholders of such a resource, and their willingness to recruit participants in a future trial
 - Acceptability of the developed resource to children and their parents, and their willingness to be recruited to a future trial

6.4.5 Data analysis

6.4.5.1 Quantitative element

Simple descriptive analysis was undertaken for clinical and socio-demographic characteristics as well as recruitment, retention/completion rates and attendance (instances where the child was not brought for treatment/did not attend school).

All statistical tests were undertaken using SPSS™ software v29. The Shapiro-Wilk test was completed to ascertain if the data was parametric (normally distributed) or non-parametric (skewed). Where data were shown to be parametric, a paired t test was employed. If data was found to be non-parametric, a Wilcoxon signed rank was used. The range, mean, median, and standard deviation of each sample was calculated.

The standard deviation for the data obtained from the candidate outcome measures (the VAS, CFS and IPS-Anx C) was calculated to help to inform the estimated sample size required for a future trial. The reliability of the IPS-Anx-C was additionally investigated through calculation of the Cronbach's alpha to determine its suitability for use in future trials in this population.

Post hoc amendment

In addition to calculating the standard deviation of the candidate primary outcome measures, additional statistical analyses were completed to compare the mean scores, range of scores, and identify any items which did not show variation between participants or only scored 0. This was to allow for further consideration of the most appropriate measure and identify any potentially irrelevant items.

6.4.5.2 Qualitative element

Analysis was conducted concurrently to recruitment and data collection. A framework approach was employed using the Five Areas Model initially to guide the analysis (Ritchie and Lewis., 2003). A combination of inductive (data driven) and deductive (theory driven) coding and theme development were employed (Fereday and Muir-Cochrane 2006). The following steps were taken:

1. Transcription of data by Dictate2us (external company)
2. Familiarisation with the interviews
3. Coding and development of a working framework for analysis
4. Application of the developed framework to the dataset
5. Charting of the data into the framework matrix
6. Interpretation of findings

The researcher discussed the findings with another experienced qualitative researcher (ZM) to review and debrief following completion of an initial three interviews (mixture of families and HCPs). Participants who agreed to be contacted and members of the PPI panel were invited to comment on the analysis, to ensure they agreed with the interpretation of the data and to support analysis, as adults often misinterpret children's meaning (Huang *et al.*, 2014). Researchers FN and ZM independently read and reviewed transcripts to identify important and recurring ideas within the data. Any disagreements were resolved through discussion. The data were organised into themes. Each interview was reviewed, labelled, and indexed into a Microsoft Excel 365 database (Washington, Microsoft Corporation).

For the healthcare professionals, a framework was developed based on the first five interviews, with evidence to support each subtheme traced to the original transcript from each participant (Smith and Freeman., 2010). For each subsequent interview, ongoing analysis and discussion were undertaken to further refine each theme and subtheme until a stage was reached where no new ideas or themes could be constructed. At this stage, data collection was deemed to be sufficient for the healthcare cohort, and recruitment ceased. There were insufficient participants in the child group to reach this stage, and the framework was based on the interviews available.

6.5 Results

6.5.1 Recruitment of settings and sites

Children's hospital

The Sheffield Children's Hospital were directly approached in the first instance through their Clinical Research Facility (CRF) by the primary researcher in April 2019 and October 2020 prior to submitting the funding proposal, to explore their willingness and ability to support the study. Following the award of ethical approval in December 2022, the CRF were contacted to confirm if they would participate, which they agreed, and begin the process of receiving local approval. The process was generally smooth except for a delay in granting access for FS to recruit participants from this Trust. There was a five-month delay between the research being approved, and the lead researcher being granted access to begin recruitment (Stage One). This Trust participates and leads in multiple studies and works with two local research active universities which may have influenced their decision to participate.

Seven clinics were then formally approached to participate over a period of seven months: rheumatology, psychology, medical daycare, theatre pre-operative clinics, ophthalmology, oncology, and clinical research. Approaches were made to the lead Consultant or manager for the service in the first instance. Where a clinic did not respond within four weeks, a follow-up email was sent. If there was still no response within two weeks, FS investigated other avenues of contact (such as alternative email contact addresses or staff members such as nurse specialists). Of the clinics approached, three (43%) agreed to participate (rheumatology, ophthalmology, and clinical research), two declined (oncology and theatre admissions) and two did not respond despite multiple enquiries sent to two different email accounts in each case (medical day care and psychology). The clinics who declined provided feedback: oncology declined as their patients were a highly researched cohort and were already participating in multiple ongoing studies, and pre-operative clinics reported that they would not be able to recruit as they did not meet patients face-to-face and therefore could not consent prior to the planned procedure.

Dental hospital

The Clinical Lead for Paediatric Dentistry services at the Charles Clifford Dental Hospital was approached prior to funding application in April 2019 as part of the sponsor trust, and to explore their willingness and ability to support the study. Following award of ethical approval, the lead researcher directly liaised with the sponsor regarding local approvals. Both the main and satellite paediatric dental clinic agreed to participate. The main clinic was based within the hospital, with the satellite clinic based in a community dental clinic in an area of high dental need (S5 postcode). The primary researcher (FS) holds a clinical post in this service and was familiar with both the staff and clinics. The hospital is also attached to a research active university and has participated in and hosted multiple previous studies, which may have influenced their willingness to participate.

School settings

As described in the methods section, all schools in South Yorkshire were approached. The researcher split these into three areas: Sheffield, Rotherham and Doncaster depending on in which council area they were located as shown in table 6.1.

Area	Approached	Responded	Agreed to participate	Eligible to participate
Sheffield	31	4	3	1
Rotherham	24	1	0	0
Doncaster	14	1	1	1
Totals	69	6	4	2

Table 6.1 Number and location of schools approached to be in the study

In total, six schools responded to the invitation to participate. One school directly declined as they had an upcoming Ofsted inspection, and one school requested further information, after which they did not respond. The remaining four schools were interested in participating, Unfortunately, two of the schools who indicated an interest in participating could not facilitate the introductory presentation prior to their vaccination dates due to time and other pressures, and therefore could not be included, leaving two schools who were able and willing to take part.

School one was a comprehensive school in Sheffield, admitting students aged 11-19 years old. It has an Ofsted score of 'good'. The overall student population is over 1800 students, and the target year group consisted of 305 students. School two was a secondary school in Doncaster, selectively admitting students aged 11-16 years old. It has an Ofsted score of 'good'. The overall student population is 250, and the target year group had 50 students overall.

Results summary

All the planned settings were recruited to participate in the study. Within settings, site recruitment rates varied as shown in table 6.2 below.

Setting	Approached sites (clinics or schools) within setting	Responded	Agreed to participate	Eligible to participate
Dental hospital (including satellite clinic)	2	2 (100%)	2 (100%)	2 (100%)
Children's hospital	7	5 (71%)	3 (43%)	3 (43%)
Schools	69	6 (9%)	4 (6%)	2 (3%)
Total	78	13 (17%)	9 (12%)	7 (9%)

Table 6.2 Site recruitment summary

This demonstrates large variation between sites.

6.5.2 Recruitment of participants

6.5.2.1 Quantitative element

Participants were recruited between January and July 2024. A CONSORT-style diagram showing the flow of participants is shown below in figure 6.1.

Of the 149 assessed for eligibility, two potential participants were excluded by the lead researcher FS (1.3%). One participant became ineligible after changing their mind and declining their NBP, while another had attended alone and did not have a parent/carer present to sign their consent forms. Of the 52 eligible participants, eight declined to participate, with reasons being provided by four of these.

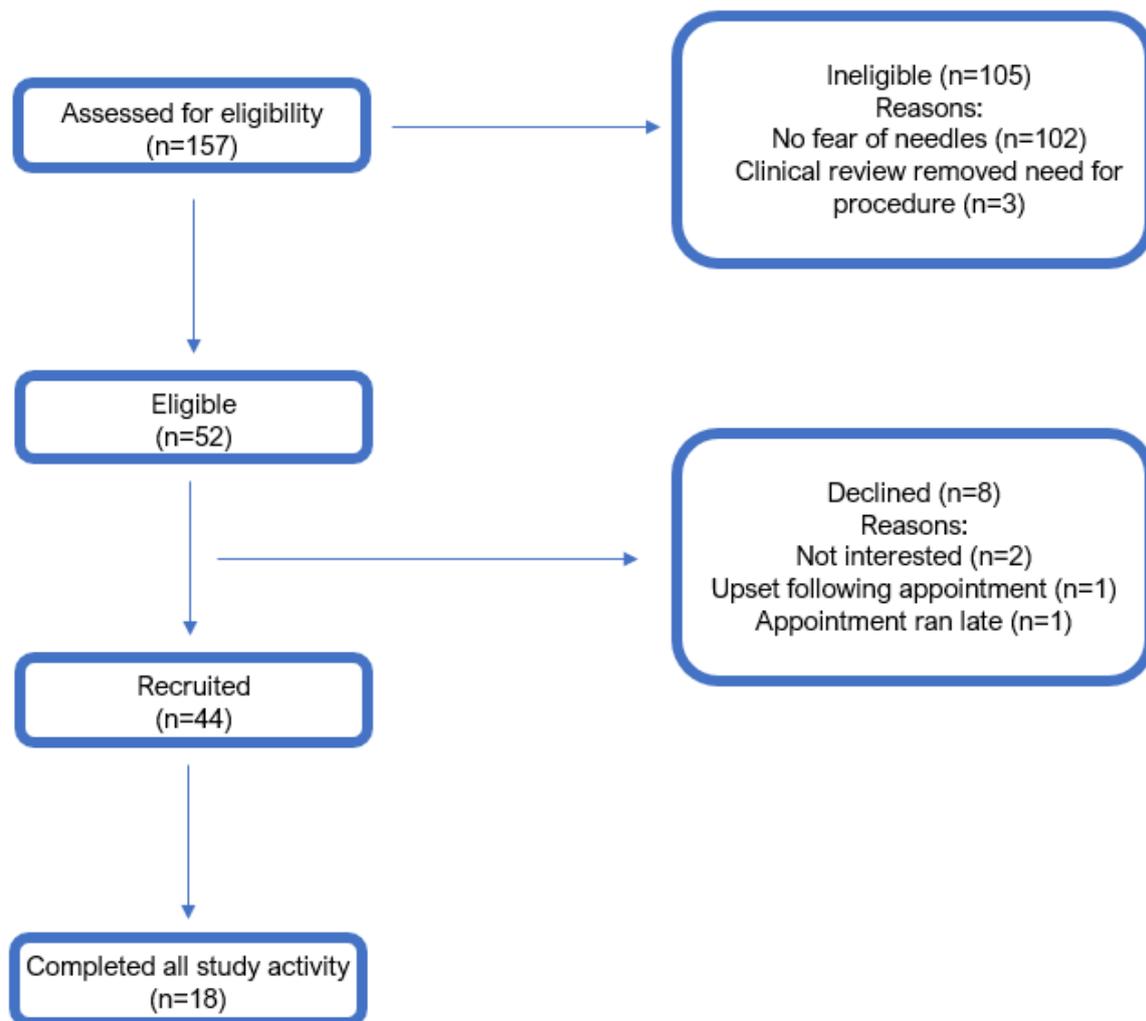


Figure 6.1: Diagram of participant flow

The detail related to each setting is shown in table 6.3 below. The primary researcher (FS) attended all settings personally to recruit.

Setting	Approached and completed screening	Excluded	Interested but ineligible	Interested and eligible	Consented (% of eligible)	Target consents	Consented (% of target)
Dental hospital	129	2	104	24	16 (83%)	20 (combined with satellite)	16 (80%)
Satellite clinic	0	0	0	0	0	20 (combined with dental hospital)	0 (0%)
Children's hospital	20	0	0	20	20 (100%)	20	20 (100%)
	Approached at assembly			Interested and eligible		Target	
School 1	256	0	0	3	3 (100%)	10	3 (30%)
School 2	34	0	1	5	5 (100%)	10	5 (50%)
Totals				52	44 (80.7%)	60	42 (70%)

Table 6.3 Summary of participants recruited by setting

Overall, 105 young people who were approached and indicated an interest in the study were deemed ineligible to participate. The reasons for ineligibility were that the young person did not have fear of needles on completing the screening question or that their clinical review determined that they did not require the planned/suggested NBP.

Again, the data demonstrates large variation between sites, with those who had a larger pool of 'potential' participants having the lower recruitment rates than sites with a presumed smaller potential population.

6.5.2.2 Qualitative element

Young people and parent/carer

Only those who had completed both baseline and follow up questionnaires were invited to participate in interviews. Table 6.4 summarises the eligibility, response, and completion rates.

Setting	Feasibility study participants	Consented interview invitation	Eligible to be contacted	Responded	Completed interview
Dental hospital	16	14 (87.5%)	8	2	1
Children's hospital	20	20 (100%)	5	5	2
School 1	3	1 (33.3%)	1	0	0
School 2	5	4 (80%)	3	0	0
Totals	44	39 (89%)	17	7	3

Table 6.4 Summary of participants recruited for the qualitative component of the study

Subsequently, three young people completed interviews with their parent/carer.

Although most young people indicated that they were happy to be contacted about the interviews many were not eligible to participate as they had not completed their study questionnaires. For those who were eligible and were contacted, most did not respond. This indicates either that the emails were not delivered, were forgotten, or overlooked, or the participant did not wish to participate.

The findings from the completed interviews are discussed in Section 6.4.1, below.

Healthcare professionals

In total, 15 HCPs were invited to participate in interviews following their involvement with recruiting or treating participants in the study. Of the 15 approached, 13 (86.7%) agreed to be interviewed.

Most participants were female, which was not unexpected as the clinical workforce in both hospital settings was predominantly female. Due to the involvement of clinical staff in helping promote the study in each setting many participated as both 'recruiters' and 'treaters'.

Most of the HCPs approached were happy to participate in interviews. One declined due to work scheduling concerns and the other did not wish to participate. One participant who consented to taking part subsequently withdrew from the study due to being on extended leave from work.

Almost all the HCPs arranged face-to-face interviews within their working hours, with one being interviewed at their request online while on leave. The HCPs from the children's hospital setting opted to participate in a group interview as they had overlapping availability. The high positive response rate from this group could be explained by them being reasonably research active as a whole and having an interest in participating in research as clinicians, and their belief in the project itself with a desire to help young people.

The findings from these interviews are discussed in section 6.4.1, below.

6.5.3 Quantitative results

6.5.3.1 Demographics

Child participant demographics are shown in Table 6.5 below, showing total numbers and individual to each setting. There was a reasonable split of male (40.9%) to female (59.1%) overall. No participants selected a gender other than male or female. Most participants came from areas with the highest levels of deprivation (IMD 1-3, 45.2%) with only 18.2% from areas of lowest deprivation (IMD 8-10). The majority indicated their ethnic background to be White British (90.5%) with other ethnicities including White European, Black African, White and Black Caribbean and Black Mixed Race.

	Dental Hospital	Children's Hospital	Schools	Total (n,%)
Gender				
Male	5	10	3	18 (40.9%)
Female	11	10	5	26 (59.1%)
Ethnicity				
White British	14	19	7	40 (90.9%)
White European	1	0	0	1 (2.3%)
Black African	0	1	0	1 (2.3%)
White and Black Caribbean	0	0	1	1 (2.3%)
Black mixed	1	0	0	1 (2.3%)
IMD score				
1	5	5	1	11 (25%)
2	1	4	0	5 (11.4%)
3	2	1	0	3 (6.8%)
4	1	0	1	2 (4.5%)
5	3	2	2	7 (15.9%)
6	0	2	2	4 (9.1%)
7	0	2	2	4 (9.1%)
8	2	0	0	2 (4.5%)
9	1	4	0	5 (11.4%)
10	1	0	0	1 (2.3%)

Table 6.5 Demographic details for child participants

Other details collected included history of NBPs and level of worry. These are displayed in table 6.6.

	Dental Hospital	Children's Hospital	Schools	Total (n,%)
Worry				
Very Worried	10	8	2	20 (45.5%)
A little bit worried	6	12	6	24 (54.5%)
Previous procedures				
Yes	16	20	8	44 (100%)
No	0	0	0	0 (0%)
Type of previous procedures				
Vaccine	15	20	7	42 (95.5%)
Intravenous injection	4	13	1	18 (40.9%)
Blood test (arm)	11	19	2	32 (72.7%)
Intra-oral injection	13	9	3	25 (56.8%)
Blood test (finger prick)	8	17	1	26 (59.1%)

Table 6.6 Additional participant data collected at baseline

Table 6.6 shows that there was an almost even split of young people selecting 'very worried' (45.5%) vs 'a little bit worried' (55.5%). Participants were also asked which NBPs they had experienced previously. All the participants had received at least one previous type of NBP previously, with vaccines being the most common (95.5%). This is not unexpected, as these are a scheduled NBP for all healthy young people in the United Kingdom. The second most common previous procedure was a finger prick blood test (59.1%).

The female: male split of those indicating 'very worried' and 'a little bit worried' is shown in table 6.7.

	Female	Male	Total
Worry			
Very Worried	15	5	20
A little bit worried	11	13	24

Table 6.7 Worry results displayed by gender

6.5.3.2 Procedures

Participant planned procedures are shown in Table 6.8 below, showing total numbers and individual to each setting. Of the initial 42 participants recruited, only those who completed their follow-up questionnaires could be assessed for success of procedure. None of the school participants provided information about the success of their vaccination.

	Dental Hospital	Children's Hospital	Schools	Total (n,%)
Planned procedure				
Blood test	1	9	0	10 (22.3%)
Cannula	1	1	0	2 (4.5%)
Dental LA	14	0	0	14 (31.8%)
Intravenous medication	0	2	0	2 (4.5%)
Joint injection	0	8	0	8 (18.2%)
Vaccine	0	0	8	8 (18.2%)
Procedure completed?				
Yes	7	4	0	11 (57.9%)
No	1	0	0	1 (5.3%)
Unknown	1	1	5	6 (36.8%)
Reviewed website?				
Yes	6	4	0	10 (52.6%)
No	1	0	0	1 (5.3%)
Unknown	2	1	4	7 (42.1%)

Table 6.8 Participant procedures and success

Most participants' planned procedure was dental local anaesthetic (31.8%). This was not unexpected, as most of the young people attending the dental hospital setting would be undergoing this single procedure while in the children's hospital setting there were more potential treatments in different specialties. Of those who completed the study activity and provided responses (n=18), information about the success of the procedure was available for 12. Clinical success was confirmed either by the young person or the treating clinician. Of these 12, most completed their planned procedure (11/12 - all in hospital settings). None of the school cohort advised if they had received their vaccine and as this was an external setting which was not attended on procedure day, it was impossible to clinically confirm if the vaccines had been administered. Children were asked directly if they had reviewed the website, when administering the follow-up questionnaire. Information was available for 11 children, as one questionnaire had been given to the child by a clinician who did not ask about the site. Of these 11, most stated that they had looked at the website (10/11).

6.5.3.3 Retention and completion rates

Retention and completion rates are shown in Table 6.9 below, showing total numbers and individual to each setting. Completion rates were low overall with the highest being in the school settings (62.5%).

	Total	Dental Hospital	Children's Hospital	Schools
Withdrawals	0	0	0	0
Completion of baseline and follow-up questionnaires (% of participants)	18 (40.9%)	8 (50%)	5 (25%)	5 (62.5%)

Table 6.9 Withdrawals and completions

Overall, of the 44 consented participants 18 young people completed both the baseline and follow-up questionnaires (40.9%). No participants formally withdrew from the study.

General factors which were observed to interrupt participant ability to complete the second questionnaire included:

- Timing of follow up appointments (scheduled months after recruitment and out-with the study window either due to normal timing or waiting lists)
- Hospital cancellations (staff illness or leave)
- Patient cancellations
- Rescheduled appointments where research team were not notified

One patient in the children’s hospital setting was not brought to their planned follow-up appointment as the parent had forgotten.

The lowest completion rate was observed in the Children’s Hospital setting (25%).

6.5.3.4 Outcome measures

As described previously, all participants were asked to complete three outcome measures at both baseline and follow-up.

The descriptive summary of all 44 baseline questionnaires is shown in table 6.10 below.

	No of questionnaires	Minimum	Maximum	Mean	Median	Std. Deviation
VAS ¹	44	0	100	53.27	56	28.87
CFS ²	44	0	4	2.93	3	1.23
IPS-Anx C ³	44	1	53	21.7	19	12.08

¹ Where 0 indicates ‘not at all worried’ and 100 indicates ‘extremely worried’

² Where 0 indicates the least worried and 4 indicates the most worried

³ Where 0 indicates the least worried and 72 indicates the most worried

Table 6.10 Descriptive summary of baseline outcomes (including responses from all 44 completed questionnaires)

The results included in the following sections are based on completed data only, i.e. those who completed both the baseline and follow-up questionnaires.

Visual Analog Scale (VAS)

The mean score at baseline was 53.11, ranging from 0-100, with a standard deviation (SD) of 31.75. The mean score at follow-up was 37.93, ranging from 0-82, with an SD of 22.73.

The data showed a normal distribution with a Shapiro Wilk sig. value of >0.05 . A paired t-test was therefore used to analyse the data. The paired samples correlation suggests that the samples are strongly positively correlated (0.819) and this is statistically significant ($p < 0.001$). There was a statistically significant difference in the scores at baseline and follow-up; $t = 3.483$ $p = 0.003$.

Children's Fear Scale (CFS)

The mean score at baseline was 3, ranging from 0-4, with a standard deviation (SD) of 1.24. The mean score at follow-up was 1.61, ranging from 0-4, with an SD of 1.09.

The data showed a normal distribution with a Shapiro Wilk sig. value of >0.05 . A paired t-test was completed to analyse the data. The paired samples correlation suggests that the samples are moderately positively correlated (0.697) and this is statistically significant ($p = 0.01$). There was a statistically significant difference in the scores at baseline and follow-up; $t = 6.43$. $p = 0.01$.

Injection Phobia Scale – Anxiety Children (IPS-Anx C)

The mean score at baseline was 20.83, ranging from 1-40, with a standard deviation (SD) of 12.14. The mean score at follow-up was 18.72, ranging from 0-41, with an SD of 12.75.

There were no items without some variation between participants.

The data were found to be normally distributed with a Shapiro Wilk sig. value of >0.05 . A paired t-test was completed to analyse the data. The paired samples correlation suggests that the samples are strongly positively correlated (0.867) and this is statistically significant ($p = < 0.001$). There was a non-significant difference in the scores at baseline and follow-up; $t = 1.392$; $p = 0.091$.

Cronbach’s alpha was calculated, to determine the reliability of the questionnaire, with a score of 0.899. This suggests high reliability for the IPS-Anx C in this cohort. The item total statistics results suggest that the Cronbach’s alpha *could* be increased through removal of certain items (4,8,14,15) which would improve the reliability. The corrected item correlation of these items is also low, suggesting that in future if researchers wished to omit these items, it would not negatively impact the overall reliability of the measure.

Some items in the measure have low corrected item correlation, and their removal would improve the reliability – items 4,8,14 and 15.

6.5.4 Qualitative results

6.5.4.1 Demographics

Participant demographics are shown in Tables 6.11 and 6.12 below, showing total numbers and individual to each setting.

Setting	Participant type	Age	Gender	Ethnicity	Pseudonym
Children’s Hospital	Child	12	Male	White British	Ronaldo
	Parent	NA	Female	White British	Jennie
	Child	14	Male	Black African	Jimmy
	Parent	NA	Female	Black African	Sarah
Dental Hospital	Child	14	Female	White British	Sofia
	Parent	NA	Female	White European	Monica

Table 6.11 Demographics of interview participants (young people and parent/carers)

Setting	Job role	Gender	Study role	Pseudonym
Children's hospital	Specialist nurse	Female	Recruitment	Beyonce
	Specialist nurse	Female	Recruitment	Cleopatra
	Specialist nurse	Female	Recruitment and treatment	Beryl
	Specialist nurse	Female	Recruitment	Imogen
	Specialist nurse	Female	Recruitment	Penelope
Dental hospital	Research nurse	Female	Recruitment	Tabitha
	Research nurse	Female	Recruitment	Linda
	Administrator – patient bookings	Female	Recruitment	Ladasha
	Administrator – clinic co-ordination	Female	Recruitment	Consuela
	Dental nurse	Female	Recruitment and treatment	Florentina
	Dentist	Male	Treatment	Austin
	Dentist	Female	Treatment	WITHDREW
School	School nurse	Female	Recruitment	Alana

Table 6.12 Demographics of interview participants (healthcare professionals)

All children opted to participate with a parent, with one interview taking place at the Children's Hospital and the other two taking place at the University of Sheffield. All the healthcare professionals were interviewed at the University of Sheffield. All the participants were known to the researcher (FS) prior to conducting the interview, as she had worked with them or recruited them during the study. The findings from these interviews are discussed below.

6.5.2.2 Young people and parents

In total three young people and three parents participated in interviews following their participation in the feasibility study. Due to the low number of participants who were eligible and agreed to take part, the qualitative data is limited, and therefore the subsequent analysis was also limited. The domains covered within the interview were: thoughts on the resource, experience of participation, outcome measures, willingness to participate in future randomised studies and improvements to design. Figure 6.2 maps the factors related to these domains.

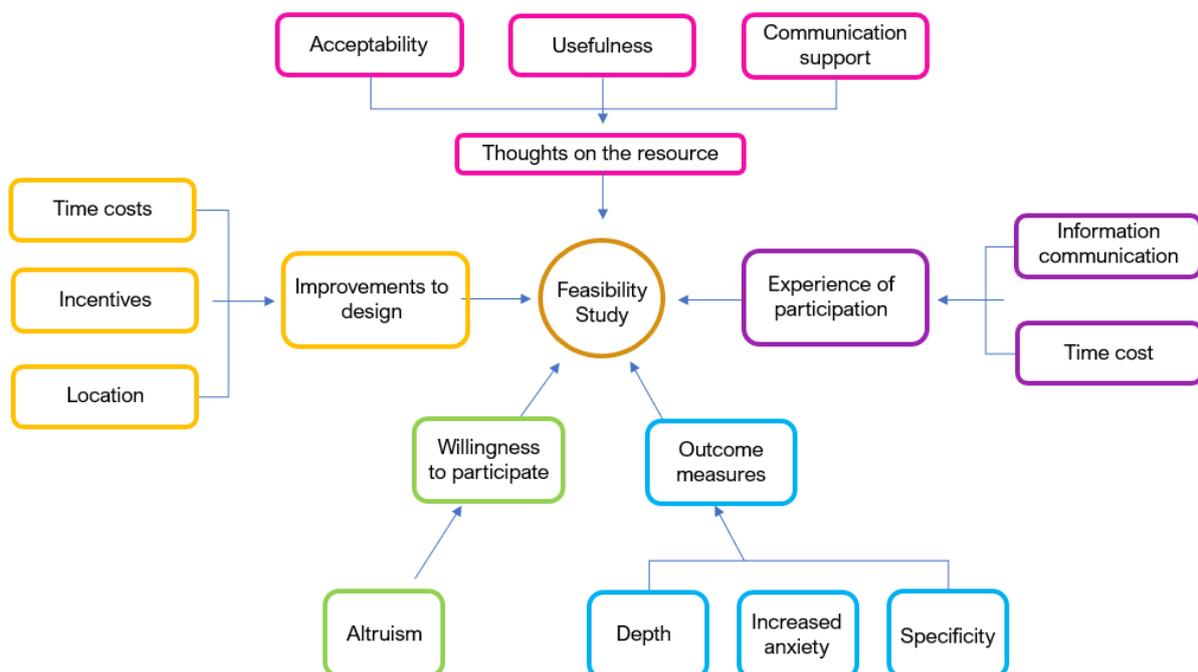


Figure 6.2 Diagram mapping children's experiences of study participation

Thoughts on the resource

This domain relates to the No Need(l)e To Worry website, the development of which is described in Chapter five. Important themes in this domain were: accessibility, usefulness, and communication support.

Accessibility

Within this theme, young people and parents demonstrated their belief that the resource was simple to use.

'It was quite easy to use'

Jimmy, 14-year-old (yo) male

'You've managed to make it accessible, you know, in so many options'

Monica, mother of Sofia

Usefulness

Within this theme, young people and parents discussed their experience of the resource being practically helpful to them.

'I felt better coming in today because I knew about this [website]. I wasn't scared this morning, and last night – I'm usually petrified of going to sleep.'

Ronaldo, 12yo male

'I think overall it was quite a very helpful site. There were lots of areas they covered, so it wasn't just a one-page document for parents'

Sarah, mother of Jimmy

Communication support

With regards to communication support, young people described their thoughts about the communication tool which was developed. They particularly liked that it could be hidden from others if wished and could be tailored to their individual needs.

'Some people may not want like other people knowing that like they have to go to appointments or things like that, and so obviously having it concealed is like, I suppose it just gives more privacy'

Jimmy, 14yo male

'It customises what I like, and it's not what the doctor likes it's what I like'

Ronaldo, 12yo male

'Especially if you're nervous and you're not very comfortable speaking to people you don't really know, and you can have it right in front of you'

Sofia, 14yo female

This suggests that the resource is acceptable in its current format to these young people and parents.

Experience of participation

This domain relates to the experience of the young people and parent of participating in the quantitative element of the study. Important themes in this domain were: information communication and time cost.

Study information

Within this theme, young people and parents discussed their appreciation of the information given to them before deciding to take part in the study. All young people and parents felt that they had been well informed about the study.

'You definitively covered like every question that I would have, and every concern'
Jimmy, 14yo male

'It wasn't confusing or anything, it was quite easy to read'
Ronaldo, 12yo male

'I thought it was very informative, as I say I'm Head of Legal Services and an Information Governance specialist and I was very impressed with your explanations'
Jennie, mother of Ronaldo

Time cost

Within this theme, young people discussed the low time cost of taking part in the study.

'I didn't think it was too complex or time consuming which was obviously good'
Jimmy, 14yo male

'It didn't take too much time'
Ronaldo, 12yo male

This suggests that the participant information sheet content was comprehensive, and that the study activity was an appropriate length.

Outcome measures

This domain relates to the three candidate outcome measures (VAS, CFS and IPS-Anx-C) which young people were asked to complete at baseline and follow-up.

Opinions on the use of the outcome measures were mixed, with the CFS appearing least popular. Important themes in this domain were: depth, increased anxiety, and specificity.

Depth

Within this theme, young people described their thoughts on the depth achieved by each measure.

*'Either the line [VAS] or the 18-question one [IPS-Anx C], but I think not the faces one [CFS] because there was only like a certain amount that you could pick from'
'Maybe the longer one [IPS-Anx C] because it gives more in-depth specific questions'*

Jimmy, 14yo male

'Faces [CFS] is just how I wanted to feel, but if you put it in writing you could put I feel worried, and you could put why you were feeling worried'

Ronaldo, 12yo male

Increased anxiety

Within this theme, a young person described his thoughts on specific items within a measure. He disliked the injection specific items within the IPS-Anx-C.

'I just didn't really like talking about injections [IPS-ANX C]'

Ronaldo, 12yo male

Specificity

Within this theme, a young person described her thoughts on the most specific measure for recording needle fear.

'Probably the line [VAS] because it's very specific'

Sofia, 14yo female

This suggests young people will have different needs from outcome measures to represent their needle fear, and that some measures may result in increasing their anxiety simply through its completion.

Willingness to participate

This domain relates to the willingness of participants to participate in a future study, which would be randomised. The main theme in this domain was altruism.

Altruism

Within this theme, young people indicated that they would be happy to participate in a study, even though they may not receive the resource, for the 'greater good'.

'It will help other people even if it doesn't really help me'

Jimmy, 14yo male

'Knowing that it's going to help other people and it's for a good cause'

Sofia, 14yo female

Improvements to design

This domain relates to the design of the study, and how young people could be supported to participate in future similar works. Important themes in this domain were: time costs, incentives, and location.

Time costs

Like the domain 'experience of participation', young people described how time costs of a study could influence others in terms of their willingness to participate in research.

'Being quick and not time consuming is really important for a lot of people'

Jimmy, 14yo male

Incentives

Young people felt that having an incentive, or reward for taking part, might encourage some people to take part.

'I would still do it if there was no voucher, but like having the gift vouchers is just a bit more exciting'

Sofia, 14yo female

Location

The location of a study was also considered important, as increased travel could be a barrier for some.

‘Something that might put me off is if we had to travel somewhere for it’

Jennie, mother to Ronaldo

These suggestions may be useful for researchers planning research with young people in the future.

6.5.2.3 Healthcare professionals

In total, 12 healthcare professionals took part in interviews following their participation in the feasibility study, in terms of their role in either recruiting or treating young people who took part. The domains covered within the interviews were: thoughts on the resource, experience of participation, willingness to recruit to future studies, future settings, and improvements to design. Figure 6.3 maps the factors related to these domains.



Figure 6.3 Diagram mapping healthcare professionals' experiences of study participation

Thoughts on the resource

This domain relates to the No Need(l)e To Worry website, the development of which is described in Chapter Five. Important themes in this domain were: accessibility and usefulness.

Accessibility

HCPs demonstrated their belief that the resource was accessible, in both ability to access and ability to use. Overall, HCPs found the resource to be accessible and simple to use.

'I like the fact that you can listen to it, you can read it, or you can print it'

Penelope, Rheumatology Nurse

Usefulness

Within this theme, HCPs discussed their experience of the resource being practically helpful to patients.

'I personally think it's a very good idea. I think firstly because it helps to sort of help the young person to understand why they have the fear and what they can do to try and overcome that fear and express their fears'

Austin, Dentist

'I really like that it's targeted to each different like procedure'

Imogen, Eye Nurse

Experience of participation

This domain relates to the experience of the HCP of participating in the quantitative element of the study. Important themes in this domain were: information communication, researcher support, patient relationships, availability of participants, language barriers and practical restrictions.

Study information

HCPs described their experience of receiving information about the study. Overall, they felt the information provided was comprehensive.

'I felt I knew what I needed to do if I could get the right age and the right patients'

Linda, Dental Nurse

Researcher support

HCPs described the benefit of being supported by the researcher during the study, and how this was beneficial.

'I think you're very flexible in terms of what you've been able to offer, in terms of coming across, because I think it's easier to actually meet people face-to-face'

Cleopatra, Rheumatology Nurse

'You being there and it not just being on a PowerPoint project for me to just show them, it gives a bit of personability to it'

Alana, School Nurse

Patient relationships

HCPs described the benefit of their clinical relationships in being able to recruit to the study, through targeting their efforts on those they felt might be eligible.

'I've enjoyed it. I think it's the advantage I suppose is that we know the patients and we know which ones have anxiety over any of the procedures'

Beryl, Rheumatology Nurse

Availability of participants

The dental hospital HCPs reported specific issues around locating eligible patients and organising participant follow up appointments that were not shared by the participants from other settings.

They reported difficulty reaching recruitment targets. This was sometimes due to cancellations or target patients not being brought to their appointments.

'We've had a lot of cancellations while I've been doing them'

Linda, Dental Nurse

'I think I see more missed appointments from anxious patients'

Austin, Dentist

Some recruiters felt that there was a lack of eligible patients booked to attend.

'Sometimes you'll have nobody on the session'

Florentina, Dental Nurse

'I think one day I was like 'oh, there might be four here' and that was the maximum'

Linda, Dental Nurse

There were clinics which by their nature should have included reasonable numbers of eligible participants, however these were often booked with unexpected patients.

'Unfortunately, with our clinics, there's quite a few that book appointments and as much as you try and keep control of one clinic to put patients in, other people have access to it and soon it's full of anything and everything'

Ladasha, Clinic Admin Support

An additional barrier which was noted was difficulties in organising and keeping track of the follow up appointment for the participants.

'We don't answer the phone, so when people cancel it's a bit harder to keep track of them and let you know'

Consuela, Clinic Co-Ordinator

Language barriers

Health care professionals from both hospital sites discussed their difficulties in recruiting where parents could not read or understand the study information or consent form as these were only available in English.

'Supposed to come with an interpreter and they cancelled on the day'

Linda, Dental Nurse

'If we've not got an interpreter for that patient or sometimes, they speak really good English but they might not be good at reading it'

Florentina, Dental Nurse

'All of your information is in English and there's probably a few patients we can think of that wouldn't be their first language'

Cleopatra, Rheumatology Nurse

Design restrictions

The study design was identified by some HPCs as problematic in some areas. They discussed how certain restrictions had presented challenges to their recruitment of potential participants. A lack of physical space was reported, and that the researcher and recruiters did not have a specific assigned space to work.

'I think that is challenging, trying to talk to patients in a waiting area. I would say that's actually the biggest barrier is actually having somewhere quiet to sit and go through it all'

Beryl, Rheumatology Nurse

Some felt the age range eligibility criteria prevented them from recruiting patients.

'I was thinking of age range as well, I've got some 10 and a half or 10 and three quarters who would be great for the study but obviously aren't in the age criteria'

Penelope, Rheumatology Nurse

The school participants reported difficulties with the informational assemblies and pupils being generally unengaged. The assembly for the larger school had been held in a gymnasium with many children compared to the second school which was significantly smaller.

'I think looking at it now the first school was what, 300 children? We could have split it down to a smaller group because I don't think it was really well heard.....it weren't very personal with 300 kids all messing around in a morning in a hall.'

Tabitha, Research Nurse

Some children were felt to lack engagement with the idea of the study as a result of this approach.

'They were too busy doing their own thing'

Tabitha, Research Nurse

'Some [kids'] puberty has set in, and their hormones are all over the place and they go through Kevin and Perry phase as I call it – oh I can't be bothered'

Alana, School Nurse

These highlight both facilitating aspects and challenges of the study method which researchers may look to address in future similar studies.

Willingness to recruit

This domain relates to the willingness of HCPs to recruit in a future study, which would be randomised. The main theme in this domain was necessity.

Necessity

Within this theme, HCPs described their understanding that for research to provide quality evidence, sometimes randomisation is required.

'If it doesn't happen at all [randomising] then the results aren't going to exist'

Cleopatra, Rheumatology Nurse

'Yeah, because that's how you do the research, there's no other way'

Florentina, Dental Nurse

'Then you've got a non-biased comparison to make haven't you, between different groups'

Alana, School Nurse

'I think it's worth doing because it's the end result'

Tabitha, Research Nurse

This suggests healthcare professionals are willing to recruit for a randomised trial in this research area.

Future study settings

This domain relates to the thoughts of HCPs on which settings should be included in a future study to test the developed resource. The main themes within this domain were benefit to participants and benefit of setting.

Benefit to participants

HCPs described how they felt that children in their setting would benefit from being included in a future study.

Most felt that they would like their setting to be included to benefit young people.

'A school sample, they're not always used to being injected. Some of them have only ever had the vaccinations and a lot of them haven't had them for years'

Alana, School Nurse

'I think especially in dentistry, that is what most people are scared of and have had terrible things when they were children, so if you know you can do something to alleviate that'

Consuela, Admin Support

Benefit of setting

HCPs described how they felt that their setting would be beneficial to include in a future study.

HCPs felt that the setting would have a good population of potential participants, and in some cases could even be expanded.

'Yeah, because I think you're going to get most of people in schools that have got a fear'

Tabitha, Research Nurse

'It'd be nice if you could have a bit more of a community [dental] setting as well'

Linda, Dental Nurse

Improvements to design

This domain relates to the design of the study, and how recruitment could be improved. Important themes in this domain were: study length, recruitment strategies, electronic media, and incentives.

Length

HCPs discussed that the length of the feasibility study had been too short to allow effective recruitment.

'Open for longer would be helpful'

Linda, Dental Nurse

'It might need to be longer [than 6 months]'

Florentina, Dental Nurse

Recruitment strategies

HCPs discussed that the participants numbers could be improved and supported through adjusting the recruitment strategies.

Some suggested improving access to potential participants through booking strategies.

'I think it needs to be more targeted bookings [booking in patients specifically who may be eligible]'

Linda, Dental Nurse

'You could set up specific clinics, you would have to grade them and write in the comments that it needs to be for this study'

Consuela, Clinic Co-Ordinator

For school settings, it was felt that purposefully targeting smaller schools would be helpful.

'I think probably picking smaller schools'

Tabitha, Research Nurse

Electronic media

HCPs discussed that the use of electronic study documentation may support more participants in taking part.

This was felt to be potentially beneficial as it could be more accessible.

'A video they could watch, maybe that's a couple of minutes, and we can say have a look at this'

Imogen, Eye Nurse

'Some of the adolescents in earlier research-y stuff that a colleague has done have said they prefer paper stuff, so there is a divide of who likes electronic and who doesn't, but I suppose the option would be nice'

Beryl, Rheumatology Nurse

It was also considered that some young people may not want others to know about their participation in the study, and electronic media could allow them to keep this private.

'Perhaps if they could do it online and say I've got a fear, and no one would know you might get more people taking part'

Tabitha, Research Nurse

Incentives

In terms of facilitating recruitment, HCPs discussed that, for school settings in particular, incentives may be useful in future.

'Probably giving them [teachers] an incentive for it. I don't know, like a voucher or something like that'

'And it gives a bit more positive publicity to the school doesn't it really, if public and the students that attend here notice that we do actually actively take part'

Alana, School Nurse

'A lot of BRIGHT [study] ones were recruited because they got money'

Tabitha, Research Nurse

Many of these suggestions could improve the study in future and enable the recruitment of more settings, sites, and participants. They would also address some of the issues encountered by the lead researcher (FS) and are worth considering in the design of future studies.

6.6 Discussion

This stage of the study involved assessing the feasibility of the study protocol and obtaining methodological evidence to inform the design of a future trial to evaluate the developed resource. Additionally, young people, parents and healthcare professionals shared their thoughts on the acceptability of the resource in its present format.

Most appropriate self-report measure

The first uncertainty to be addressed was the most appropriate self-report measure of needle fear. The study tested three measures chosen through review of the published literature and input of the core PPI group – the VAS, CFS and IPS-Anx C. It should be noted that for each of the measures, the data is based on a simple before and after comparison, and therefore the findings do not provide evidence that the resource is effective but can indicate a plausible signal of efficacy.

The VAS was observed to have strong positive correlation between paired samples, and a statistically significant difference between mean scores at baseline and follow-up. Comparing the scores from this study to others where the VAS has been used as a measure of needle fear in children is difficult due to differences in study designs. Many studies do not use the VAS as a self-report tool, and others take the measure only after the procedure has been completed, while this study has recorded two measurements pre-procedure. This was considered more appropriate, as a child's needle fear may decrease after a procedure due to the natural relief that the procedure is over. Studies which take only post-procedural scores additionally cannot assess for change. Two studies which did record needle fear prior to a procedure were those by Dufresne and colleagues (2010) and Brenner and colleagues (2013). Their intervention groups had mean scores of 27.3 and 43.1 respectively, compared to this group who had a pre-intervention score of 53.11. The scores are like those reported by Brenner and colleagues (2013). However as neither of these studies screened for needle fear during recruitment, their study populations could be composed of a higher proportion of children with low or no level of needle fear. This makes direct comparisons difficult. Children taking part in this study liked that the VAS was quick to complete and found it 'specific'.

The CFS was observed to have a moderate correlation between paired samples, and a statistically significant difference between the mean scores at baseline and follow-up. The CFS has been used widely in the published works on needle fear, but it is occasionally used with proxy reporters rather than its intended use as a self-report measure. The CFS has been used to measure change in needle fear in children in many published works, including those by Stolz and Manworren (2017), Ankan and Esenay (2020), Özkan and Polat (2020), Abdullah and Suat (2023), Çelik and Düzkaaya (2024), Düzkaaya *et al.*, 2024; Kirbaş and Kahrıman (2024) and Savaş, Semerci, and Bayram (2024). The pre-procedural mean scores reported in these studies vary, ranging from 1.11 to 4.46 which is broadly in keeping with the mean score of 3.39 in this study. It is worth noting that again, none of these studies specifically recruited children with needle fear which may account for some of the lower scores reported. Children in the study reported disliking the CFS scale due to its use of faces.

The IPS-Anx C was observed to have a strong positive correlation between paired samples and a non-statistically significant difference between the mean scores at baseline and follow-up. The IPS-Anx C has not been frequently used in the published literature. Having been developed during the PhD study of its creator (Oar 2015), it has only been used in one internal study by the same author, and this reports only its reliability (Cronbach's alpha 0.94) and no scores or other properties. This is similar to the Cronbach's alpha in this study (0.899), both of which suggest high reliability.

The measure cannot be otherwise compared as it has not been used in any other studies to date, to the authors knowledge. Children in the study had mixed feelings about the IPS-Anx-C. It was felt to collect the most information but might make some people anxious due to its reference to specific procedures. Children did not comment on the length of the IPS-Anx-C negatively.

All three measures were completed appropriately by all participants and showed promise for use in a future trial. The IPS-Anx C is the longest measure and gives the most clinically useful data as it includes specific items rather than an overall measurement. It does not presently have a defined 'scoring system' related to mild, moderate, and severe fear, and does not have a minimally important difference. Further work should be undertaken to provide a more robust assessment of the psychometric properties of the measure. The VAS and CFS were able to generate statistically significant differences in scores and are single item measures which are time efficient and can be adapted to fit different procedures. The CFS scale may be disliked by some young people due to its use of a faces measure. Within this study all measures were completed without issue and no clear consensus was gained from the interviews regarding which would be best applied in future. The evidence from this study suggested that all three measures should be investigated further to determine which is the most appropriate, particularly to young people. These findings suggest that further work is needed prior to commencing a future randomised study investigating the resource, but that all measures have merit and can be considered.

Perception of resource and willingness to recruit

The second uncertainty was the perception of key stakeholders on the resource, and their willingness to recruit participants. The HCPs who were interviewed about the resource included dentists, research nurses, rheumatology specialist nurses, eye nurses and dental nurses. The qualitative interviews revealed that HCPs found the resource to be accessible for patients. This referred to the different information formats included (written, graphic or audio information) as well as the ability to access on or offline. The resource was also felt to be useful for patients, through enabling them to understand worry as a wider concept and how to help address it. A key benefit was observed to be the separate sections for different procedures, allowing young people to access specific information depending on their needs.

Willingness to participate can be judged through both the engagement with the feasibility study, and the findings from the semi-structured interviews. Some difficulties were encountered in accessing sites, which did not hamper the study overall, but this issue could be considered for future research to allow sites which are likely to be engaged and have capacity to be preferentially included.

Once sites were determined, the clinical staff in each were found to be open and receptive to participating, and happily aided the lead researcher (FS) in identifying the most appropriate times to attend and suggesting patients to approach who met the eligibility criteria. Many clinicians also briefly discussed the study with patients who attended out with the researcher's attendance and contacted her to attend (either immediately or at the patient's next appointment). In the interviews, all HCPs indicated that they would support and participate in a future randomised study to investigate the effectiveness of the resource. These findings suggest that the resource is acceptable to HCPs in its current format and indicates that the study is feasible in relation to clinician willingness to recruit.

Feasibility of recruitment

The third uncertainty was around the feasibility of recruitment. All three planned settings were recruited (100%). Within each setting, the recruitment rates for individual sites varied. Within the children's hospital setting, seven clinics were approached, with three agreeing to participate (42.8%), within the dental hospital setting, two sites were approached, both of whom agreed to participate (100%) and within the school setting 69 sites were approached and four agreed to participate (5.8%). There were some challenges around the recruitment of school sites, resulting in an amendment to the protocol to include a wider geographical area.

On reflection, there are several reasons why so many approached schools may not have responded. Educational settings are under increasing pressures to provide high quality education to students with national staff shortages, increasing budget cuts, and the likelihood of Headteachers receiving a high number of emails to manage daily. It may be that the emails for the study were considered low priority, or that these were not passed to Headteachers in the first place. Without direct consultation it is difficult to ascertain reasoning. However an amendment to either the design or approach would be needed to encourage more participation. While the study did meet its aim of including school sites, in future larger studies it would be beneficial to consider methods of encouraging higher interest in participating. One such method would be to offer schools an appropriate compensation to cover the administrative burden of being involve in the study. No thank you gift or fee was offered to the schools taking part during the study during recruitment, although FS provided a small gift to the nurses and administrators who organised the assemblies and collection of paperwork. It was suggested in the qualitative interviews that a reward should be provided in a future trial to thank them and provide recompense for the staff time used. The nature of such a reward could be explored with schools to ensure it is appropriate and of value.

It could also be considered from the outset whether a large geographical area should be included, and engaging with Multi Academy Trusts who control many schools. This could result in a higher number of interested sites and ensure a more representative sample of the population is included in the trial. This should be explored at an early stage of the protocol design.

Another consideration for a future trial, will be the number of sites within each setting. To meaningfully measure the effectiveness of the resource, and identify any facilitators and barriers to use, it will be important to test it in as many different sites as possible. It should also be ensured that it is tested with a range of different NBPs. Within the feasibility study, it was challenging to recruit within the Children's Hospital setting, with many of the approached specialities failing to respond. There are several reasons which may account for this. It may be that the staff members who were invited were too busy to consider the invitation, too busy to participate, or that the email invitation did not reach a member of staff able to make the decision on whether to participate. The emails may have been redirected into spam folders, and therefore never received. It is also possible that the settings were uninterested and chose not to respond. To improve the recruitment of varied healthcare settings, it will also be important to include the site at an early stage of the protocol design and planning to help identify interested settings, and to overcome any obvious barriers to their participation.

Considering participant recruitment, in the quantitative element of the study, the overall recruitment rate was good (70%). The pool of eligible participants was reasonable, with 50 of 159 young people approached being eligible (31.4%) and 42 of those agreeing to participate (76.3%). The lowest recruitment rate was observed in school settings, with a target of 20 and a final sample of eight (40%). In school settings, it was surprising to the researchers that the school with the larger cohort only provided three participants while the small school provided five. This may have been due to the sheer volume attending the introductory assembly in the larger school, and the experience feeling less personal than for the small cohort. There is also the possibility that some children could not hear or see the presenters properly due to the set-up of the hall, felt self-conscious about asking questions with such a large audience, or that children influenced each other as to whether to take part. The HCPs who were involved with the school settings agreed that the low recruitment rate was likely to be due to the engagement of the children at each site. Children may be more comfortable and likely to engage in smaller groups. Additionally, only two sites were recruited for this study, and it may have been beneficial (considering the potential for low engagement) to include a larger number of sites.

To address some of the challenges encountered with recruitment of participants from school settings, it will be important to involve schools at an early stage of the design process to seek their advice on best methods of recruitment in their school. Consideration should be given to working with pupils in smaller groups, which may improve engagement but will be more laborious and time consuming for the research team and may be more disruptive to the schools. Teachers should therefore be consulted to ascertain the best methods.

In relation to the healthcare settings included in this study, good recruitment rates were achieved for both settings and participants (80% of target at the dental sites and 100% at the children's hospital). This may, at least in part, be since these were research active hospitals. They have had recent positive research experiences and successes, and the sites are generally very open to participation in projects. There are also clearly established pathways for registering projects. It is not clear if the settings or sites would have been as easy to recruit in a hospital with less research activity. Further work should be undertaken to explore the possibility of undertaking the protocol in hospitals with little to no ongoing research activity. Although the recruitment rates were very good at these sites, there were some areas which could be improved, particularly to include participants from a wider variety of sites. A general recommendation for future studies which could aid in increasing recruitment rates would be an electronic consent process. It would enable more sites to participate, particularly those who do not currently see patients face-to-face, and allow participants to complete their forms prior to attending which would save time at their clinical appointment. As mentioned above in relation to completion rates, it would also be beneficial to provide the study questionnaires electronically, so that this could be completed prior to attending, and this would also save even more clinical time. It would also mean that a researcher does not need to be present at each appointment, reducing researcher time pressure.

In the qualitative element of the study, the target number is indicative only, as recruitment must cease when no further relevant information is gained. Based on the indicative targets, the recruitment rate for HCPs was very good (87%) but for young people and parents was very poor (15%). This can be partly explained by the limitation of only being able to invite those who had completed both their initial and follow-up questionnaires, reducing the pool of potential participants (40.9%). Overall, from the 18 young people who completed the study, 17 had given consent to be contacted for invitation to interview (94%). Of the 17 contacted, all had asked to be emailed with the information. Most did not respond to the email invitation which may indicate that they did not wish to take part, or that the emails were not read or delivered. This suggests that email follow-up may not be the best method of contact for invitation to interview, even though this was given as the preferred method of contact by these participants.

Seven participants responded to the email invitation (41.2%) and agreed to be interviewed. All wished to be consented at a time and date tied to their next hospital appointment, which often fell outside the study timescale. Efforts had been made to ensure that the interviews were as accessible as possible, with FS offering face-to-face, virtual or telephone options, but the same consideration had not been given to the consent process. FS offered to complete consent forms on the same day as the interview, but this was only beneficial to those wishing face-to-face interviews. Overall, three were recruited and completed their interview. The introduction of electronic consent forms would be beneficial as participants could complete this remotely and the interview could then be undertaken via telephone or virtually if no face-to-face appointments were pending, or they did not wish face-to-face. Another factor which may have influenced recruitment is that this cohort are anxious and may not wish to discuss this sensitive topic with others/adults. There were similar challenges in recruiting for the qualitative interviews in stage 1. Further work should explore how this can be overcome, perhaps using alternative media, or perhaps involving young people in small groups where they discuss with other young people or family members rather than researchers.

Retention and completion rates

The fourth uncertainty related to retention and completion rates. The overall retention rate for the study was 100% (as no participants were 'lost' to follow-up or withdrew), and the completion rate was 40.9% (18/44). Several factors were identified which contributed to the low completion rate such as the length of the feasibility study (6 months), being incompatible with the length of time between appointments (particularly for patients recruited toward the end of the study window), cancellation of planned appointments (by the site or patient) and administrative errors (researcher not informed of changes to appointments). The lowest completion rate was observed in the children's hospital, likely due to the larger gaps between the initial appointment and return date for the planned procedure, which was normal for the setting, but resulted in many patients not receiving their procedure before the study window closed – preventing them from completing the study activity. The highest completion rate was observed in the school setting, possibly due to the questionnaires being sent and returned electronically.

To mitigate the issues with completion in a future study, several options can be considered. To overcome difficulties encountered in patients returning for their follow-up appointments within the study time window, the data collection period should be extended to a period of at least 12 months following closure of the recruitment window. This should also be discussed at the early stages of planning with the potential clinical sites, to ensure this would be a long enough period for patients to be expected to return for treatment.

This should also mean that patients with cancelled appointments could still return within the study period. Another potential consideration which would mitigate the issues with the researcher missing the follow-up due to rescheduling would be to offer the option of providing follow-up questionnaires electronically. This would allow the participant to complete their paperwork even if the appointment date or time was amended, and to return it directly to the research team. These findings suggest that some small amendments to the study protocol would result in an improvement in the completion rates for a future randomised study.

A recent similar paper with better completion rates is that by Bray and colleagues, who published the result of their feasibility study in 2024. They were also investigating an intervention for young people with needle fear, an app to prepare them for blood sampling, and assessing its acceptability to children, parents, and healthcare providers. The authors of this study recruited children from a slightly different age range (six -14 years old) over a shorter timeline (three months). These participants were recruited prior to their attendance in the clinical setting through telephone contact and provision of the app, completing their paper consent when they attended for their blood test. Like this study, children were asked to complete study questionnaires before and after their blood test, and it was recorded whether their procedure was successful. The researchers do not state a target sample size, but contacted 47 families, 24 of whom agreed to participate (51%). Of those 24, 20 completed both questionnaires (83.3%) – a higher proportion than observed in this study (40.9%). This is likely since participants completed all their study documentation in a single visit. The participants who did not complete their follow-up questionnaire are reported to have been too upset after their procedure. The writers conclude that the app is acceptable based on the feedback from the stakeholders. They acknowledge that their sample was small, and a convenience sample of interested patients attending a clinic – meaning that the parents who agreed may have been predisposed to give positive feedback, as they were engaged with preparing their child for the procedure. No demographic information was recorded, so it is unclear if the sample would be representative of the general population. It was also felt that participants may have been under pressure to provide the ‘right’ answers to the team as they handed back their questionnaires immediately after the procedure, meaning they may have worried about anonymity.

The higher completion rate for the study is desirable, however the approach taken by Bray and colleagues could not be applied in full to the current study (Bray *et al* 2024). It is essential that for a future trial to evaluate the resource, confounding factors are mitigated as best possible. It is considered that a patient’s anxiety/fear levels will naturally decrease after a procedure, as the procedure is no longer looming.

This means that the outcome measures should be completed prior to their procedure, to ensure any reduction can be attributed to the resource and not simply the relief that their treatment is completed, and therefore the paperwork must be completed at two different timepoints. It is however feasible that patients could be contacted ahead of their appointments and offered information about the study, to reduce the time taken on their clinical session. Interested parties could then complete their consent and baseline questionnaire immediately on arrival to their initial appointment or may even be able to consent and complete paperwork beforehand. This may prevent declines due to distress or appointments running late. Parents would also be aware that they would need to attend the first appointment if they wished their child to take part.

Acceptability of resource and willingness to be recruited

The final uncertainty was the acceptability of the developed resource to children and their parents, and their willingness to be recruited. The qualitative element of this feasibility revealed that young people and parents found the resource to be acceptable and useful. Young people spoke about accessibility in terms of ease of use, while parents felt it was accessible due to the number of options for engaging (reading, listening, or looking at drawings). The resource was seen to be useful in that young people had found it made them less worried about their procedure, and parents felt that the parent section was comprehensive and provided them with a lot of helpful information and strategies. These findings were based on a small number of participants, and it would be beneficial to explore acceptability with a larger number of young people and parents to identify any areas which could be improved.

Willingness to be recruited can be judged through the findings from the semi-structured interviews. The young people interviewed all indicated that they would be happy being recruited to a future study and appreciated the need for randomisation in a future study, as did their parents. Given the small number of participants recruited to the qualitative element of the study, it would be prudent to explore this further prior to proceeding with a larger scale trial. This study also did not explore what the control group would be for a future trial as it did not investigate 'usual care'. It will also be important to define this prior to future trial.

Overall, the findings of this feasibility study indicate that the protocol is feasible for use in a randomised controlled trial to investigate the effectiveness of the resource. It is recommended that further work be completed to further improve the protocol, to ensure that the trial could be run to maximum effect and efficiency, improving the quality of evidence that will be obtained.

It is also recommended that the resource undergo further review with a wider cohort, to ensure it addresses the needs of a larger population and gain insight into any improvements which could be made to its effectiveness, inclusivity, or accessibility. In the interim, given the acceptability and potential benefit of the resource, it should be disseminated more widely to allow young people across the United Kingdom to access support with their needle fear. This will be achieved through dissemination to young people, parents and healthcare professionals to maximise reach.

6.7 Conclusions

The following conclusions can be drawn from the work presented in this Chapter:

1. The protocol is feasible with amendments
 - a. Electronic consent forms should be offered to improve recruitment of sites and participants
 - b. Data collection period should be at least 12 months from the closure of the recruitment window
 - c. Further work should be undertaken to explore an effective and appropriate recruitment plan for school settings
 - d. Further work should be undertaken to assess the implementation of the protocol in research limited settings
 - e. Further work should be undertaken to determine how best to engage young people with needle fear in qualitative elements
 - f. Further work should be undertaken to assess the most appropriate primary outcome measure for future trial
2. The resource is acceptable to young people, parents, and healthcare professionals in this cohort

Chapter Seven

7. Discussion

Needle fear in children is common and can have wide reaching impacts on their quality of life and ability to receive healthcare interventions. It is essential that young people can access resources to support them in managing NBPs. In the literature review, summarised in Chapter 2, the need for a resource to support young people with needle fear was discussed and explored. The lack of present resources was highlighted, and the NICE (2015) recommendations for mental health treatment access reviewed.

This thesis has established through qualitative interviews described in Chapter Four that young people can be negatively affected by their fear of needles and would welcome a self-help online resource to support them in managing their fear. Having appreciated this, a resource was then co-designed with young people, parents and healthcare professionals as discussed in Chapter Five. This resource was then tested in an uncontrolled feasibility study, reported in Chapter Six to obtain methodological evidence to inform the design of a future trial to assess its effectiveness.

An individual discussion on each stage of the study was included at the end of each Chapter, specific to the work undertaken. This Chapter therefore provides an overarching discussion of the strengths, limitations, ethical considerations, clinical implications, and research implications of the study.

7.1 Key findings and limitations

7.1.1 Stage 1: Qualitative interviews

The objective of this stage was to undertake qualitative interviews with children, young people, and their families to gain a meaningful insight into their experiences of needle fear, and preferences for a self-help resource to address needle fear.

The key findings were:

1. Young people can be negatively impacted by fear of needles, and they worry about how this might affect them longer term.
2. Young people and parents had a strong preference for a resource which was hosted online with printable elements.

3. Young people and parents felt it would be beneficial to include information about worries, different procedures, and coping strategies alongside a communication tool for use with healthcare professionals.

The limitations of this study related largely to participant diversity, interview settings and recruitment sites.

Participant diversity

The diversity of the included participants could have been improved in relation to gender, ethnicity, and sample site. In Sheffield, according to the most recent Census (Office of National Statistics, 2021) the local population is 79.1% white, while this cohort was 91.7% white. Females comprise 50.6% of the local population and 66.7% of those interviewed which is not overly dissimilar, but it would have been beneficial to include more male voices in the interviews. As discussed briefly in Section 4.6, it was challenging to recruit both male participants and those from other ethnic backgrounds. It is an established fact within the literature that there are significant challenges in the inclusion of young males in both anxiety and mental health related research (Ellis *et al.*, 2014; Drioloi-Phillips *et al.*, 2021) This is thought to be related in some cases to stereotypical cultural norms, where males are expected to be strong, masculine and brave and it is seen as undesirable to admit to anything which could be perceived as a weakness by others (Connell and Messerschmidt, 2005; Wong *et al.*, 2017). It is also an established fact that it can be challenging to recruit participants from non-White backgrounds in research more generally (Spencer *et al.*, 2022; Premji *et al.*, 2020). This is a priority for researchers, and work is being undertaken by NIHR nationally, as well as local and regional groups, to help encourage and support the participation of under-represented groups. Future work is required to explore the cultural factors which may influence young people's experiences of needle fear and preferences for self-help resources.

Interview settings

Interview settings could also have influenced the findings of this stage through the location and people present. All young people asked to complete their interview face-to-face. Most young people opted to be interviewed in their home (66.7%), where they likely felt most comfortable. This may have supported them in feeling confident and safe to share their thoughts and experiences. The remaining four young people (33.3%) asked to complete their interview in a room chosen by the interviewer (FS). The University of Sheffield was chosen as the venue for these participants, as the researcher felt this was more neutral than a clinical setting.

This likely felt more formal than a home setting, and these young people may have felt less comfortable. The researcher took steps to improve the comfort of all young people, including providing them with drinks and snacks of their choice, but the setting was an office room with a window and a table set up like a workshop or interview. This may have caused these young people to treat the experience as more of a task than an informal chat, meaning they may have felt more pressured to provide the 'right answer'. The option of the University room was usually chosen by these participants to tie in with a local appointment, reducing their travel, which may have improved their willingness to participate but potentially at the cost of some meaningful data.

The interviewer (FS) offered to complete the interviews separately or together regardless of the interview setting and posed the question to the child rather than the parents. Most of the young people also opted to complete their interviews with their parent or carer, with only one interviewed separately. The influence of parent's presence during child qualitative interviews has been discussed in the literature and can be helpful or unhelpful depending on several factors. Parents' understanding and support of their children can provide richer data but conversely some parents may speak for their children and prevent the child's voice being heard meaning a solo interview would allow for richer data (Gardner and Randall, 2012). These effects can also be seen even if a parent is only occasionally or peripherally present (Wiedenman, Lee and Hunleth, 2023).

Being interviewed alongside a parent was observed by the interviewer (FS) to be advantageous in some circumstances, where a parent prompted their child to share an experience, recalled additional elements of the experience, or could support their child in sharing their thoughts. It is not possible to comment on whether the child shared less detail because of the parental presence, although it may have been difficult for the children to answer the questions asked on the influence of their parent's behaviour to avoid upsetting or angering their parents.

In future research, individual interviews should be considered in this age group to facilitate the voice of the child, but young people should always be offered a choice of whether to have a parent/carer present.

Recruitment sites

The final important limitation of the interviews was the recruitment setting. Due to difficulties with recruitment at the hospital medical setting caused in part due to administrative difficulties in local registration of the study, only one clinic could prepare to participate within the timeline.

This pre-operative clinic managed patients for assessment prior to general anaesthetic, including those referred to a 'procedural anxiety' pathway which provided an excellent recruitment opportunity. Unfortunately, this clinic was a telephone assessment and therefore participants could not be directly consented which negatively impacted the recruitment process and led to no participants being recruited. All participants were therefore recruited from the dental site, where many of them had been referred for treatment due to anxiety around dental local anaesthetic. This led to an increased reference to dental treatment and experiences over other medical needle-based experiences, although many young people had experiences beyond dental anaesthetic which were shared during the interview. This is possibly due to the treatment which young people were due to receive, and this being at the forefront of their mind during the process. The experiences of young people who were due to undergo different needle-based procedures (NBPs) may have been very different and involved additional factors. Therefore, the experiences of this cohort may be more impacted by their upcoming dental treatment experiences and not represent the additional factors specific to other treatments or settings.

Future research should ensure that participants are recruited from a wider range of settings.

7.1.2 Stage 2: Co-designing the resource

The objective of this stage was to use a co-design approach with children, carers, and healthcare professionals to develop a self-help resource.

The key findings were:

1. Young people, parents and healthcare professionals can be effectively engaged as collaborators through a co-design approach
2. Co-design can engage collaborators to discuss potentially distressing topics in a constructive way
3. Co-design activities work effectively in both face-to-face and online settings
4. Young people and parents prefer website-based resources with the option to print off resources to expand inclusivity

5. Co-design supports flexibility and adaptation of study processes to meet the needs of individual collaborators

The limitations of this study included ethical approval and collaborator diversity.

Ethical approval

Co-design is not a research activity, rather it is a design process. As it is not classed as research, formal ethical approval is not strictly required. It is also an emerging methodology which is not often well described in the published literature, leading to misunderstanding and perhaps reluctance by some to learn about and employ this approach in their work. It is difficult to find detailed examples of work undertaken by others, particularly in healthcare. This is in part due to difficulty in publishing works as some healthcare journals decline to publish articles in the absence of ethical approvals. To share the knowledge and learning from this study, a decision was made to seek ethical approval from the University of Sheffield to provide a basis for use of the data in future publications.

Being awarded ethical approval ensured that the findings would be accepted for publication but as a piece of work classed as research activity this necessitated obtaining formal consent from participants and presented an additional step in the recruitment process which could be a barrier for some potential collaborators.

The collaborators were recruited from the local population through social media. Posters were shared on major social media sites X™, Instagram™ and Facebook™ requesting that interested parties contact the lead researcher (FS) for further information. Although several enquiries were made, it was difficult to organise completion of consent forms in some cases. The researcher did not speak to those interested directly, instead communication by Facebook™, X™ or email in the first instance. This 'virtual' recruitment may have hampered the ability to develop initial rapport with potential collaborators. It is likely that a process which had not required formal consent may have resulted in higher numbers agreeing to take part at an earlier stage, reducing the delay in commencing this stage of work.

Future enquiry should consider the pros and cons of seeking ethical approval for non-research processes, and plan for the effect this may have on recruitment or willingness to participate. Co-design is a design process, rather than research, and therefore does not require ethical approval.

As previously referenced, lack of formal ethical approval does not mean a researcher will not act ethically, and in fact obtaining formal approval can create many barriers within a project – particularly through the time required to submit the application and have this approved, and in creating a requirement for collaborators to complete formal consent forms. It can also confuse and create misunderstanding from colleagues and the public, who may then consider that co-design is in fact a research process.

The decision was ultimately taken, with advice from senior colleagues, due to the number of researchers who have encountered challenges when trying to publish their work in high impact healthcare journals without ethics approval. This is likely to be due to journals having become accustomed to authors submitting these documents as part of ‘standard’ research projects. While the ethics approval does demonstrate that ethical consideration was given to all aspects of the method, there are other ways to provide this evidence through clear documentation in manuscripts, reports and other written works related to projects of the considerations made and steps taken to mitigate risks to collaborators. It should also be carefully considered whether if healthcare researchers continue to seek and obtain ethical approval for co-design projects, rather than being prepared to challenge journals and others about the nature of the process, this will simply encourage and foster a culture where it will become impossible to complete co-design work without ethical approval. As healthcare researchers begin to embrace design as part of working with our target users (usually patients), and the practice becomes more comfortable and commonplace, we should consider reporting our ethical practices in line with other styles of work which do not require ethical approval, such as quality improvement projects.

Collaborator diversity

The diversity of the included collaborators could have been improved in relation to gender and ethnicity. In Sheffield, according to the most recent Census (Office of National Statistics, 2021) the local population is 79.1% white, while this cohort were 92.3% white. Females comprise 50.6% of the local population and 85.7% of the collaborators. As discussed in detail in Section 7.2.1 above, it is a known challenge to include both males and those from non-White backgrounds in research.

Future work is required to explore the cultural factors which may influence young people’s preferences for the design and content of the self-help resources.

7.1.3 Stage 3: Uncontrolled feasibility study

The objective of this stage was to undertake an uncontrolled feasibility study to address the following uncertainties:

1. The most appropriate self-report measure of needle fear (which will be the primary outcome for the future trial)
2. The perceptions of key stakeholders (such as phlebotomists, dentists, anaesthetists, research nurses) on the resource and on their willingness to recruit participants
3. Feasibility of recruitment
4. Retention and completion rates
5. Acceptability of the resource to children and their parents, and their willingness to be recruited

The key findings were:

1. All planned settings (100%) were recruited to the study, although there were challenges in recruiting the school setting
2. Participants were able to be recruited from each setting, but amendments are recommended to improve recruitment rates in future work
3. The completion rate was 40.9%
4. Healthcare professionals are willing to recruit to future randomised studies
5. Young people and parents in this study are willing to be recruited to future studies, although further work should be undertaken to determine if this is acceptable to a larger population
6. The resource is acceptable to the young people, parents, and healthcare professionals in this study, although further work should be undertaken to determine if it is acceptable to a larger population

The limitations of this study related to participant diversity, recruitment within settings, completion rates and poor interview recruitment.

Participant diversity

The diversity of the included participants could have been more representative of the local population to ensure generalisability of findings. According to the most recent Census (as above, ONS 2022), the local area is 79.1% white while this cohort were 90.9% white. In relation to gender, the diversity was more in keeping with the local area which has 50.6% females, with the study cohort having 59.1%. It would have been beneficial to achieve closer representation. As discussed in greater detail in Chapter 7.2.1 above, it is a known challenge to include those from non-White backgrounds and males in research.

A future study must consider methods of recruiting a more representative population, with particular focus on including more participants from non-White backgrounds. This could include incorporating the recommendations from the STEP-UP report for clinical trials (2021) such as including (but not limiting to) selecting sites in under-represented areas, conduction of equality impact assessments, engagement with stakeholders from under-represented groups, improving communication through use of simple language or alternative formats, use of interpreters, flexible recruiting, and researcher training. Additionally, the NIHR INCLUDE (2021) project contains key definitions, questions, and recommendations for improving inclusivity in research. Another method of achieving better representation in studies is through working with local and regional partners with experience in this area. At the time of writing, the local Children's hospital in Sheffield have recently appointed a community outreach research nurse, who's role focuses on the inclusion of under-represented communities in research through building of relationship and trust. Consideration should also be given to how to support participants and/or parents who may not speak or read English fluently, such as providing information in other languages (verbally and/or written) and using more visual information. The involvement of individuals in similar roles or with experience of working with the target populations should be sought at early stages to ensure a robust recruitment strategy.

Recruitment within settings

Recruitment of and within the school setting was particularly difficult in this stage of the study, for several potential reasons. Schools were initially difficult to recruit, as described in Chapter 6, leading to a wider geographical area being included in the recruitment process. Only six of 69 approached schools responded to the invitation email. This is likely due to the high workload of schools and Headteachers, which may have led to these emails being overlooked. Some schools who were not interested will have simply not responded, rather than reply to indicate this.

This suggests that a wide geographical area must be applied to approach as many schools as possible. Where schools did reply and indicate interest, two could not facilitate the introductory presentation in time. An attempt to mitigate this issue had been made through working with the local vaccination team, who had indicated their willingness to assist by providing the vaccination schedule for Sheffield schools. This would have allowed the primary researcher (FS) to preferentially target schools who would have time to facilitate the presentation, and those who had vaccinations scheduled too early in the academic year would not have been approached. Unfortunately, this information was not provided, and therefore some schools received invitations who could not then participate despite their interest. It was also noted that this vaccination team were only contracted to provide services to some Sheffield schools, with others receiving care from privately outsourced companies. This means that a vaccination schedule may not be possible to obtain in all areas and therefore cannot be used to plan recruitment. Engagement with schools earlier in the process (rather than the vaccination team) would have been more beneficial, as they would have known their own schedule, and could have facilitated earlier recruitment of this setting.

Future work should ensure schools across a wider geographical area are included and that schools are consulted early in the process to plan attendance and any research processes.

Difficulties recruiting participants within school settings included the introduction of the study being targeted at too large a group, and the requirements for young people to return physical packs to the school office. Working with a large initial group may have prevented some young people from engaging adequately with the information or being reluctant to ask questions in front of peers. The school with a smaller setting provided a larger number of participants, which supports the idea that introducing the research to small groups may be more effective. As part of the research process, young people who wished to take part were required to return a 'pack' to the school office, which had been provided to them during the introductory presentation. This may have prevented some young people from taking part, as it did not ensure anonymity as they may have been observed by classmates returning the envelope to the school office.

A future study should therefore consider informing school pupils about research in small groups and the use of electronic consent methods, to enable young people to sign up while maintaining privacy and anonymity. It will also be important to include schools early in the planning process, to ensure a robust recruitment and consent plan which does not interfere with academics and allows the school to engage.

Completion rates

Completion rates for this stage of the study were poorer than hoped, with 40.9% completing both the baseline and follow-up questionnaires. In healthcare settings the completion rate was 44.4% in the dental hospital and 25% in the children's hospital. The main reason for this in healthcare settings was a failure to return for the planned procedure within the study window. In the hospital setting, these patients may have had their next procedure planned for three or four months after they were recruited to the study, particularly affecting those receiving joint injections. This prohibited them from completing their second questionnaire prior to the study window closing. In the dental setting, there are presently long waiting lists for treatment. At the time of writing this thesis, the waiting time in that service for an appointment with local anaesthetic alone is three months and for those requiring inhalation sedation, the waiting time is five months. The waiting times at the time of preparing the study proposal were significantly lower, but changes within the service including staffing levels and referral rates have impacted this greatly. This again prohibited some participants from being able to complete their follow-up questionnaires within the study window.

It would also be important for a future study to consider the most appropriate length of time for follow-up and make provisions for the possibility of additional stresses on the setting causing delays to patient care.

In school settings the completion rate was 62.5%. The main reason for failed completion in school settings was a failure to return the electronic questionnaire. This was more commonly observed in the case where a school email address was provided. It is possible that the school filter did not allow the follow-up email to be sent, or that this email was filtered into the student's spam folder. This would mean the young person could not return the second questionnaire. This had been observed in one school where the school nurse contact had not received an email from the researcher with an attachment, while previous emails had been received without issue. This may have been avoided if the questionnaires had been provided through a link or QR code rather than an attachment.

Future work should consider how school participants will receive follow-up questionnaires and identify if these can be delivered electronically prior to commencing formal recruitment.

Poor interview recruitment

A final limitation to this stage was the limited number of young people and parents who participated in the qualitative interviews. The number of eligible participants was lower than expected due to low completion rates in healthcare settings, so improving completion rates may have improved the uptake of invitation to interview. It could also be considered that the inclusion criteria were too strict, by requiring participants to have completed both baseline and follow-up questionnaires. Allowing any recruited participant to participate may have resulted in a higher recruitment rate for the qualitative element of the feasibility study. In addition, of those who were eligible, and had consented to be contacted, some did not respond. This is likely due to many requesting contact via email, which was then potentially ignored, overlooked, or filtered into spam. Contact via telephone may have resulted in higher numbers agreeing to participate. Some participants who were willing to take part in interviews, wished to complete this virtually. This could have been provided, but they had not yet consented for this part of the study, and therefore were asked to either complete this face-to-face, or to scan and return a consent form. No interested participants returned forms via email. Some were happy to complete consent forms but wanted to tie this in with an upcoming appointment, which did not then fall within the study window. Had participants already provided consent to participate in the interview, it may have facilitated arrangements to schedule their interview. The low number of participants has resulted in little information regarding the preference of young people for the primary outcome measure, and the overall acceptability of being recruited to randomised studies.

Future work should consider consenting participants for the interview at the same time as the feasibility work to improve recruitment rates. This is another part of the study where electronic consent may have improved recruitment rate, alongside assisting with the recruitment of additional sites within settings, and school participant recruitment. Electronic consent should be strongly considered as an option for future studies working with similar participants or settings. Further work is required to identify the preference of young people for a primary outcome measure of needle fear, and to confirm willingness to be recruited to randomised studies.

7.2 Implications for practice

Overall, this study provides evidence that young people can be negatively impacted by fear of needles. They have a desire for positive relationships with their healthcare professionals, to be given information about their procedures, and to have control over their healthcare experiences. This has implications for the clinical management of young people with needle fear.

Communication tools which support interactions between healthcare providers and young people have been developed over the last 10 years, often targeted at a specific condition or healthcare setting (Rodd *et al.*, 2019; Taddio and MacDonald, 2019; Carlsson *et al.*, 2020; van-Belle *et al.*, 2020). The communication tool developed in this study provides the opportunity for young people to share their worries and preferences with a variety of healthcare professionals, and its neutral name and content supports its adaptation for use in other settings beyond NBPs. The wider resource provides information about worries and different NBPs while offering support through suggested coping strategies. The study shows that the resource is acceptable to young people, parents, and healthcare professionals.

The self-help nature of the resource enables young people or parents to utilise the resource without the assistance of a healthcare professional, meaning young people can seek support earlier and may attend procedures more prepared and able to cope. This resource has the real potential to improve the healthcare experiences of young people with needle fear. Although it has not been formally tested, the young people who utilised it as part of this study appear to have found it useful in managing their clinical procedures. Healthcare professionals who have been targeted for dissemination so far have responded positively to the resource, and it is likely they will find it a useful adjunct for managing their young patients with fear of needles.

The resource has been disseminated through regional and national meetings, and at two national conferences - a paediatric dental and community paediatrics conference. In practice, the resource is now being used by young people and healthcare professionals more widely, with healthcare professionals from both dental settings and schools in both England and Scotland and a psychologist in Australia having directly requested access. The maps in figure 7.1 below shows the areas where the resource is currently known to be in use.



Figure 7.1 Maps showing areas where resource are currently known to be in use

This immediate uptake highlights the real need for such a resource, and the widespread current use presents opportunities to evaluate the resource in different ways and at multiple sites, as discussed in section 7.3 below.

Further clinical and public dissemination plan

The findings of the study will be disseminated back to those who have participated in the study at an upcoming dissemination event within the university, as suggested by the pre-submission PPI group. At this event, discussions will take place to determine how young people, parents/carers and healthcare professionals would like to make use of this resource in future.

Strategies for clinical and public sharing of the website will also be discussed at the event, and guidance will be sought from an expert within the University as to the best method of utilising social media to promote the website to young people.

It is important that the resource can be given a ‘fixed address’, and the University digital expert will also guide the decision as to which website host will provide the best features to allow for both hosting of the current version, and future versions which may include different features.

7.3 Implications for future research

This study has developed, and feasibility tested a self-help tool for young people with needle fear. The resource is now in a useable format, and the feasibility study has provided some valuable methodological evidence which will be useful to researchers wishing to undertake research in a similar area, with several recommendations for amendments which will be beneficial.

Following on from this work, there are still some uncertainties which may need to be addressed prior to proceeding to a larger scale trial.

The key uncertainties are:

1. The acceptability of the resource to a wider and more representative population
2. Young people's acceptance of and preference for the candidate primary outcome measures
3. Willingness of young people to be randomised
4. Completion of study procedures
5. Exploration of usual care to define most appropriate control group
6. Recruitment of school sites
7. Recruitment of participants within school sites
8. Recruitment of a more diverse range of participants

Some of these could be addressed through small pieces of work, such as patient and public involvement (PPI) or qualitative exploration, while others would need other approaches to investigation.

It is felt that the following uncertainties could be addressed through small external work prior to the larger study.

External work prior to larger study

To address the first uncertainty, the acceptability of the resource to a wider and more representative population, it is proposed that some PPI work be completed with a diverse range of PPI representatives to identify any changes which could be made to improve the inclusivity, quality, and representativeness of the resource. Following implementation of these changes, semi-structured qualitative interviews should be undertaken with a larger sample of young people to assess their experiences of using the resource to manage their fear of needles.

For the second and fourth uncertainties, the acceptability and preference of young people for the candidate primary outcome measures, and completion rates, it is proposed that these be tested in a larger and more diverse population. This could be achieved through providing young people with the measures to complete before and after their procedure and undertaking semi-structured qualitative interviews to explore their thoughts and preferences for the most appropriate measure and quantitative analysis of the completion rates. Qualitative work with healthcare and administrative professionals should be undertaken to explore the appropriate timepoints for future trial, as well as exploration of the average waiting times within individual sites and settings.

Uncertainties three, five, six, seven and eight could be explored in the first instance through qualitative work with an appropriate sample (including young people, parents, headteachers, teachers, school nurses, young people and parents from ethnic minority backgrounds and researchers with experience in recruiting participants from under-served populations). This would allow for exploration of the willingness of young and parents to be randomised and how to improve and define the recruitment strategies for inclusion of school sites, students, and a more diverse population to maximise the chance of success. It can then be considered whether the necessary strategies for inclusion of schools will be feasible or whether there are too many practical barriers to include this setting in the full-scale trial. The exclusion of schools may be beneficial if there is concern that sufficient recruitment of the sites and students will not be possible. This could lead to the study being underpowered if an adequate number cannot be achieved. In this instance, it would be of overall benefit to the study to exclude schools to ensure the data achieved is sufficient to provide quality evidence. It would allow for a more focused study to be undertaken, focusing on the use of the resource in healthcare settings only, where recruitment was shown by the feasibility study to be of significantly less concern. The downside to the exclusion of schools is that this is a population which was identified by the healthcare professionals in this feasibility study as being important to include.

The school setting is where young people often receive their first planned needle-based procedure following on from their pre-school vaccinations. This was identified by PPI work prior to the submission for funding of this study as being an important stage, and it defined the age range for the resource. Given that this may therefore be the most likely time that young people may choose to use and benefit from the resource it is important that the resource can be tested in this setting. Completing the study in healthcare settings only would make the results less generalisable to other settings, therefore the findings of the qualitative work should be carefully considered.

As the resource is already in use across the United Kingdom (and beyond), see figure 7.1 above, there is an additional opportunity for learning and the required work listed above to be undertaken with a wider sample of the national population. This work would focus on:

1. The implementation and use of the resource
 - a) What is working well
 - b) What could be improved
 - c) Unintended uses (such as training of staff/students, use by other populations without needle fear)

2. Strategies and recruitment opportunities for a future definitive study
 - a) Could the areas where the resource is currently being adopted form part of a multi-centre trial?
 - b) Could the current sites using the resource within these areas be recruited to a definitive trial?

3. Research collaboration
 - a) Are there researchers within these areas who could form part of the research team for a future definitive trial?

Further definitive study

If it is determined that a randomised controlled trial is the next appropriate step following completion of this work, an internal pilot (as part of the definitive randomised trial) is recommended to provide additional methodological data. In particular, the internal pilot would seek to determine the recruitment rates of school sites and participants.

If the recruitment and completion numbers are good, the trial can continue as planned, and if the numbers are lower than expected, it may be that the trial protocol requires small amendments or that schools should not be recruited at all.

The internal pilot will also allow follow-up rates to be measured, and if these are low remedial action may be taken to improve them. Although no specific concerns were raised around randomisation during this feasibility study, and it is very unlikely that this will be an issue in the full trial, it would be prudent to measure the rates during the pilot to allow small amendments or remediation to be taken if beneficial.

An internal rather than external pilot trial is recommended for several reasons. The first is that the data from an internal pilot can be used within the full RCT and therefore there is no data 'wastage', while an external pilot does not allow for this. Secondly, internal pilot studies have been shown to generate better indication of true recruitment rates that may be achieved during the full trial and are likely to be a more effective use of study resources and researcher time (Avery *et al.*, 2017).

The next step following address of the uncertainties as detailed above, would be to continue to full RCT to fully evaluate the developed resource. It is suggested that this would be a parallel group trial of usual care plus the resource vs usual care alone. The study should include multiple centres, with a sufficient follow-up period as identified by the internal pilot. This is likely to be between nine and 12 months. In complement with measuring the effectiveness of the resource, it would be beneficial to complete a process evaluation and cost-effectiveness analysis.

The process evaluation would aim to examine the mechanisms of impact, contextual factors, and implementation, as recommended by the UK Medical Research Council (Moore *et al.*, 2015). Specifically, it would seek to explore the perspective of the young people, clinical and school staff and key stakeholders to understand how and why the No Need(le) To Worry resource was implemented in practice and to contribute to the interpretation of the outcome evaluation results. It will be important to consider the fidelity of the resource, the reach, any adaptations that were made and the overall acceptability.

The cost-effectiveness analysis would aim to examine the costs of the resource vs the costs associated with usual care and determine if any benefit is financially beneficial to the health service overall (Office for Health Improvements and Disparities., 2020). This may include a cost-benefit analysis to compare both health and non-health benefits such as wellbeing and convenience.

This would ensure that the costs of implementing the resource (hardware and software costs) are worth it when considering the benefits (which may include reduction in needle fear, reduction in missed appointments, reduced reliance on pharmacological support and better health outcomes).

This trial would provide better quality evidence as to the overall effectiveness of the resource in reducing needle fear in young people aged 11-16 years old and contribute to the overall evidence base for the management of needle fear in childhood.

7.4 Ethical considerations

This study was completed in accordance with Research Ethics Committee and Health Research Authority protocols.

When completing qualitative interviews with young people, several potential ethical issues had to be considered including assent, confidentiality, potential for distress and power imbalances. Steps were taken throughout the study to mitigate these risks. Young people were asked to complete assent forms if they agreed to take part, and reassured there would be no negative consequences if they did not. They were also advised that they did not have to take part even if their parent/carer wished them to. All participants were able to choose the location of their interviews, to allow them to choose somewhere they would feel comfortable. The primary researcher (FS) is a paediatric dentist, who has a wealth of experience communicating with young people, and to detect if they were uncomfortable or becoming distressed. None of the young people in this study became distressed during their interview.

There is a potential safety risk to researchers conducting interviews in participant homes. To ensure safety, FS advised her primary supervisor (ZM) of the addresses, dates, and times of all interviews. She advised when she had arrived at, and subsequently left each interview. Each of the participants who opted to complete interviews in their home were entirely welcoming, and FS did not feel unsafe at any time.

No safeguarding concerns were raised at any stage of the study. FS has level 3 safeguarding training and would have been well placed to follow appropriate procedure if any such concerns had arisen.

The study was also subject to regular progress meetings. No child, parent or staff concerns were raised during the conduction of the study.

Chapter Eight

8. Conclusions and recommendations

The study described within this thesis aimed to develop and conduct a feasibility test of a self-help resource for young people aged 11-16 years old with needle fear, based on the principles of CBT.

This chapter provides a summary of the key findings, limitations, and recommendations.

8.1 Summary of findings

1. Young people can be negatively impacted by fear of needles, and they worry about how this might affect them longer term.
2. Young people and parents had a strong preference for a resource which was hosted online with printable elements.
3. Young people and parents felt it would be beneficial to include information about worries, different procedures, and coping strategies alongside a communication tool for use with healthcare professionals.
4. Young people, parents and healthcare professionals can be effectively engaged as collaborators through a co-design approach.
5. Co-design activities work effectively in both face to face and online settings.
6. All three planned sites (paediatric dental, medical and school) were recruited to the feasibility study, although there were challenges in recruitment of the school site
7. Participants were able to be recruited from each setting, but amendments are recommended to improve recruitment rates in future work.
8. The completion rate was 40.9%.
9. Healthcare professionals are willing to recruit to future studies in this area.

10. Young people and parents in this study are willing to be recruited to future studies.
11. The resource is acceptable to young people, parents, and healthcare professionals in this study.

8.2 Summary of research limitations

1. The study population recruited to all stages may not be representative of the general population due to difficulty recruiting males and participants from ethnically diverse backgrounds.
2. The recruitment plan may have discouraged young people from taking part where they were approached in an open waiting room, or after a complex or upsetting appointment.
3. Young people were interviewed with their parents, which may have led to a reluctance to discuss the influence of parental behaviour.
4. Administrative challenges reduced the recruitment settings for the initial stage of the project and therefore did not allow for participants with a wider variety of experiences.
5. The decision to apply for ethical approval for the co-design stage may have created additional barriers to recruitment (although this created additional opportunities for sharing and publication of the work).
6. The recruitment of school settings was difficult due to the approach taken and may have prevented additional schools or pupils from participating.
7. The study window for the feasibility element was limited, meaning many participants were unable to complete their involvement within the designated timeframe. This also reduced the availability of participants for the interview element.

8.3 Clinical recommendations

1. Healthcare professionals should be aware of the proportion of young people with fear of needles, and the need for effective communication and management.
2. Healthcare and school professionals should consider recommending the No Need(le) to Worry resource to support young people with needle fear before procedures.
3. The No Need(le) to worry resources are suitable for home use by young people and parents.

8.4 Future research recommendations

1. Exploration of the cultural factors which may influence young people's experiences of needle fear and preferences for self-help resources.
2. Solo interviews should be considered in this age group to facilitate the voice of the child, but young people should always be offered a choice.
3. Efforts should be made to ensure that participants are recruited from a wider range of settings.
4. Exploration of the cultural factors which may influence young people's preferences for the design and content of the self-help resources.
5. To optimise recruitment to a future study, schools across a wider geographical area should be approached and schools should be consulted early in the process to plan attendance and any research processes.
6. It would be helpful to consider informing school pupils about research in small groups and the use of electronic consent methods, to enable young people to sign up while maintaining privacy and anonymity.
7. Consideration of the appropriate length of time for follow-up and make provisions for the possibility of additional stresses on the setting causing delays to patient care.

8. Determination should be made to how school participants will receive follow-up questionnaires, including whether these can be delivered electronically.
9. Consent of participants for qualitative interviews at the same time as the wider feasibility work may aid in improvement of recruitment rates.
10. The uncertainties which remain following the feasibility study should be addressed before a definitive evaluation is undertaken. The uncertainties outstanding are:
 - a. The acceptability of the resource to a wider and more representative population
 - b. Young people's acceptance of and preference for the candidate primary outcome measures
 - c. Completion of study procedures
 - d. Recruitment of school sites
 - e. Recruitment of participants within school sites
 - f. Recruitment of a more diverse range of participants
11. Definitive evaluation of the resource should be completed through a parallel arm randomised controlled trial including both complementary process and cost effectiveness evaluation
12. Future research in the field of needle fear should consider whether a consensus can be reached regarding use of a common measurement tool. This would allow for easier comparison between studies, and will improve the evidence base for treatment/management strategies.
13. Future research which incorporates co-design should carefully consider if there is a true need for formal ethical approval, and instead seek to demonstrate adherence to ethical practice through clear reporting.

8.5 Conclusions

Needle fear is a multifactorial experience for young people. The development of a self-help resource based on the principles of CBT has the potential to be effective in supporting young people with needle-based procedures, and to reduce their needle fear. Further research is required to assess the effectiveness of the resource in practice. The use of the website-based resource is acceptable to patients, parents and healthcare professionals and has the potential to be useful in a variety of clinical settings.

Chapter Nine

9. References

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Appendix 1 - The Applied Tension Technique

Applied tension

Applied tension is a simple technique to increase blood pressure back to normal levels so that you do not faint.

This is how you do it.

- 1 Sit down somewhere comfortable.
- 2 Tense the muscles in your arms, upper body and legs, and hold this tension for 10 to 15 seconds, or until you start to feel the warmth rising in your face.
- 3 Release the tension and go back to your normal sitting position.
- 4 After about 20 to 30 seconds, go through the tension procedure again until you feel the warmth in your face.
- 5 Repeat this sequence so that you have practised the tension five times.

If you can, practise this sequence three times every day for about a week, before moving on to facing your fear.

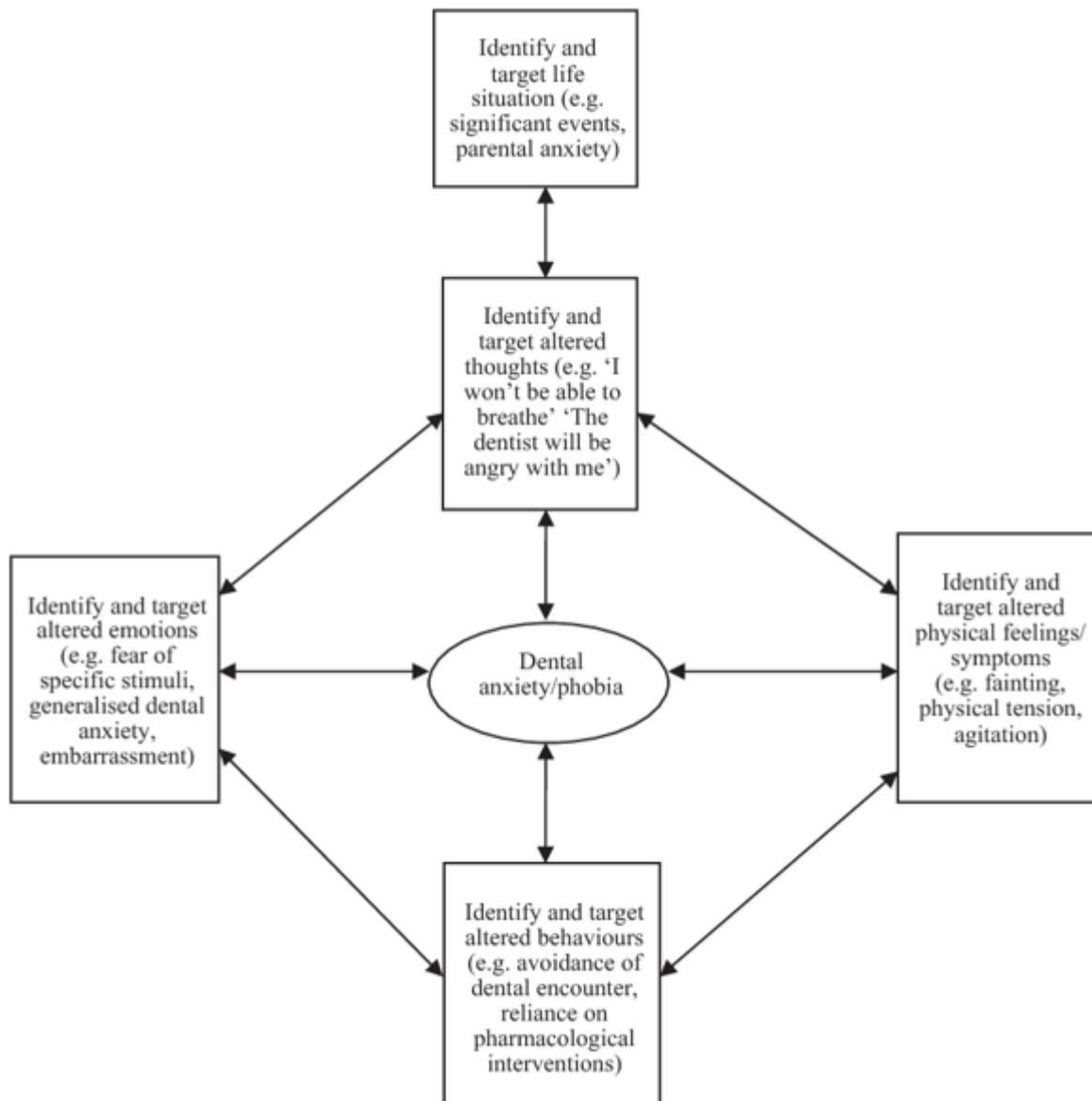
If you get headaches after doing this exercise, take care not to tense the muscles in your face and head. Also, be careful when tensing any part of your body where you have any health problems.

Appendix 2 - Example of Relaxation Technique

If you are worried about feeling panicky (heart rate increases, breathing speeds up, sweating), then try practicing a calming **breathing technique**. Try and do this 3 times a day for up to a week before your appointment:

- Sit up straight in a comfortable position and let your shoulders and jaw relax. Put one hand low on your stomach.
- Breathe in slowly and deeply through your nose and out through your mouth. Breathe as deeply as feels comfortable.
- Do this for five breaths.

Appendix 3 - The Five Areas Model applied to dental contexts



Porritt *et al.*, 2012

Appendix 4 - Initial topic Guide for Stage One Qualitative Interviews Children and Young people



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Topic Guide – Child/Young person Stage 1 interviews

Introduction

Purpose is to talk to young people about their experiences with procedures involving needles (dental injections, vaccines, blood tests, IV medicines etc) and how we might help children in the future.

Key information

- Introduce self and project (who it is for, what it is about)
- The interview will last as long as you like, probably around 30 minutes
- We will be recording what we are saying today
- This is not a test, and there are no right or wrong answers
- You don't have to talk about anything you don't want to
- You can choose a different name for us to use on the recording so we don't use your real name
- Anything we use from this interview will not be linked to your real name and we won't tell anyone else what you say
- If you change your mind about taking part, or want a break just let me know and we will stop
- At the end of the interview I will give you a voucher to say thank you for your time
- If you say anything that makes me really worried about you then I might need to speak with your parent/carer or another adult to make sure you are alright and get you any help you need
- Do you have any questions before we start?



Background

- Can you tell me a bit about yourself? (Hobbies, favourite school subjects)
- Household make up (who lives with you)
- Is there anyone you know who is worried about needles?
- How do you know they are worried about needles?

Child's experiences of needles

- Have you had any treatment before where you needed a needle? (PROMPTS: injections at the dentist, vaccines, blood test, medicine through a cannula/tap in their hand or arm, GA)
- What happened when you had your treatment?
- Do you know about any other kinds of treatment with needles? How would you feel about those?
- Has anyone you know had to have any treatments with needles?
 - How did they feel about it/manage?

Child's perception of needles/ experience of needle fear

- How do you feel when you need to have treatment with a needle?
- How does your body feel when you think about having a needle?
- What kind of things do you think about when you think of needles?
- What makes you feel worried about needles? (PROMPTS – sights, sounds, feelings)
- What kind of needles might make you worried?
- Is there anything that you can think of that might have caused you to start feeling worried about needles?
- Is there anything that you haven't been able to do because you are worried about needles?

Child awareness of tools to address needle fear

- Is there anything that you do to help you feel less worried about having a needle?
 - If yes, where did you find out about that technique?
- Is there anything that your Mum/Dad/Gran/Other adult/care does that makes you feel better?
 - If yes and present, where did they find out about that technique?
- Do you know where you could look or go for help with feeling worried about needles?

Child thoughts on a future resource

- What do you think might help children/young people who are frightened or worried about needles?
- Is there anything that anyone could have done to make it easier for you?
- Is there anything that would be helpful to do at home? Is there anything that anyone could have done to make it easier for you?
- Is there anything that would be helpful at your appointment?



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- What should a kit or materials for children to use at home look like? (prompt re heard copy/electronic if needed)
- Who should be able to use it?
- How should young people find out about it?

Closing

- Is there anything we haven't talked about today which you want me to know?
- Would you look at some things other young people have suggested to me and tell me what you think of them?
- Show ideas for website, QR code, booklet and anything else that comes up and ask for feedback

Next steps

- Thank them for taking part
- Check if they have any questions about the research
- Repeat about confidentiality and anonymity
- Remind them that the findings will be published and used to create a resource for children and young people
- The findings will be shared on the website in lay language, and we can send them a copy if they would like (confirm how to send)
- Give them their thank you voucher

Appendix 5 - Initial topic Guide for Stage One Qualitative Interviews Parent/Carers



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Topic Guide – Parent/Carer Stage 1 Interviews

Introduction

Purpose is to talk to parents, carers and young people about their experiences with procedures involving needles (dental injections, vaccinations, blood tests, IV medicines etc) and how we might help children in the future.

Key information

- Introduce self and project
- Interview will last as long as they like but usually around 45 minutes
- Interview will be recorded on a digital recorder
- Not a test, no right or wrong answers
- Don't have to discuss anything they don't want to
- Can change their mind at any time, or ask for a break
- Information provided will be anonymised
- Can choose a different name for the tape

Background

- Project is all about needles, how do you feel about needles yourself?
- Is there anyone else that you or your child knows who is worried about needles?

Their child's previous experiences

- Has (child) had treatment involving needles before?
 - PROMPT – can you tell me about them?
- Were these planned?
 - PROMPT – were they sent for immediate test/treatment or planned for a future appointment
- How did they manage at these appointments?

Parent/Carer Stage 1 Qualitative Interviews Topic Guide V1.0 (03.08.2022)
IRAS 315168
STH 20994

1



Parent awareness of child's anxieties

- How does (child) feel when they know they need to have treatment with a needle?
- How does (child) behave before their appointment or procedure?
- How does (child) react during their appointment or procedure?
- Is that out of character for them?
- Is there anything that you can think of that might have caused (child) to start feeling worried about needles?
- Is there anything that they haven't been able to do because they are worried about needles?
- Do you worry about their needle fear affecting them in the future?
 - PROMPT – in what ways
- What is the impact on the family?

Parent awareness of tools to address needle fear

- Is there anything that (child) does to help them feel less worried about having a needle?
 - If yes, where did you find out about that technique?
- Is there anything that you do to try and make them feel better?
 - If yes where did you find out about that technique?
- Do you know where you could look or go for help with (child) feeling worried about needles?

Parent thoughts on a future resource

- What do you think might help children/young people who are frightened or worried about needles?
- Is there anything that anyone could have done to make it easier for (child)?
- Is there anything that would be helpful to do at home?
- Is there anything that would be helpful at (childs) appointment?
- What should a resource for children to use at home look like? (prompt re heard copy/electronic if needed)
- Who should be able to use it?
- How should young people find out about the resource?
- Do you think parents need a tool to help their children?
- Would that be part of or separate from the child resource?
- What information would be helpful?

Closing

- Covered everything, or is there anything else you want to discuss?
- What could healthcare professionals do to make going to the dentist easier for young people?



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- What could healthcare professionals do to better support parents of young people with dental anxiety?
- Would you look at some ideas we've had from other parents and let me know what you think of them
 - Show suggested resources

Next steps

- Thank them for taking part
- Check if they have any questions about the research
- Repeat about confidentiality and anonymity
- Remind them that the findings will be published and used to create a resource for children and young people
- The findings will be shared on the website in lay language, and we can send them a copy if they would like (confirm how to send)
- Give them their thank you voucher

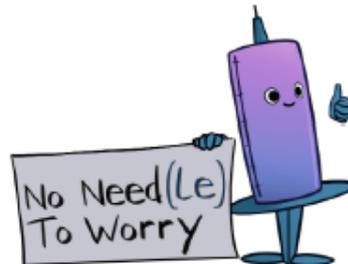
Appendix 6 - Final topic Guide for Stage One Qualitative Interviews Children and Young People



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Topic Guide – Child/Young person Stage 1 interviews

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Purpose is to talk to young people about their experiences with procedures involving needles (dental injections, vaccines, blood tests, IV medicines etc) and how we might help children in the future.

Key information

- Introduce self and project (who it is for, what it is about)
- The interview will last as long as you like, probably around 30 minutes
- We will be recording what we are saying today
- This is not a test, and there are no right or wrong answers
- You don't have to talk about anything you don't want to
- You can choose a different name for us to use on the recording, so we don't use your real name
- Anything we use from this interview will not be linked to your real name and we won't tell anyone else what you say
- If you change your mind about taking part, or want a break just let me know and we will stop
- At the end of the interview, I will give you a voucher to say thank you for your time
- If you say anything that makes me really worried about you then I might need to speak with your parent/carer or another adult to make sure you are alright and get you any help you need
- Do you have any questions before we start?



Background

- Can you tell me a bit about yourself? (Hobbies, favourite school subjects)
- Household make up (who lives with you)
- Is there anyone you know who is worried about needles?
- How do you know they are worried about needles?

Child's experiences of needles

- Have you had any treatment before where you needed a needle? (PROMPTS: injections at the dentist, vaccines, blood test, medicine through a cannula/tap in their hand or arm, GA)
- What happened when you had your treatment?
- Do you know about any other kinds of treatment with needles? How would you feel about those?
- Has anyone you know had to have any treatments with needles?
 - How did they feel about it/manage?

Child's perception of needles/ experience of needle fear

- How do you feel when you need to have treatment with a needle?
- How does your body feel when you think about having a needle? (PROMPTS: tummy/hands/shaking)
- What kind of things do you think about when you think of needles?
- What makes you feel worried about needles? (PROMPTS – sights, sounds, feelings)
- What kind of needles might make you worried?
- Is there anything that you can think of that might have caused you to start feeling worried about needles?
- Is there anything that you haven't been able to do because you are worried about needles
- Is there anything you worry you won't be able to do in the future?

Child awareness of tools to address needle fear

- Is there anything that you do to help you feel less worried about having a needle?
 - If yes, where did you find out about that technique?
- Is there anything that your Mum/Dad/Gran/Other adult/care does that makes you feel better?
 - If yes and present, where did they find out about that technique?
- Do you know where you could look or go for help with feeling worried about needles?

Child thoughts on a future resource

- What do you think might help children/young people who are frightened or worried about needles?
- Is there anything that anyone could have done to make it easier for you?



- Is there anything that would be helpful to do at home? Is there anything that anyone could have done to make it easier for you?
- Is there anything that would be helpful at your appointment?
- What should a kit or materials for children to use at home look like? (prompt re heard copy/electronic if needed)
- Who should be able to use it?
- How should young people find out about it?
- How would you look for information or help about needles?
- Where might other young people look for this resource?
- What words would you use to search online for help with needles?
- What do you think of these resources (LLTF and SCH)
- Could you use these by yourself?

Closing

- Is there anything we haven't talked about today which you want me to know?
- Would you look at some things other young people have suggested to me and tell me what you think of them?
- Show ideas for website, QR code, booklet, and anything else that comes up and ask for feedback

Next steps

- Thank them for taking part
- Check if they have any questions about the research
- Repeat about confidentiality and anonymity
- Remind them that the findings will be published and used to create a resource for children and young people
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- Give them thank you voucher

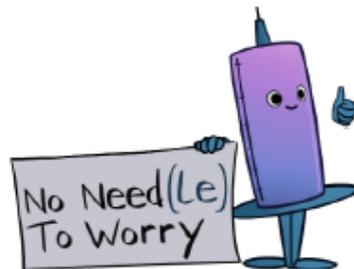
Appendix 7 - Final topic Guide for Stage One Qualitative Interviews Parent/carer



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No Need(le) To Worry: Development and feasibility study of a self-help cognitive behavioural therapy resource for childhood needle fear

Topic Guide – Parent/Carer Stage 1 Interviews

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Parent/Carer Stage 1 Qualitative Interviews Topic Guide V1.1
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STH 20994

1



Parent awareness of child's anxieties

- How does (child) feel when they know they need to have treatment with a needle?
- How does (child) behave before their appointment or procedure?
- How does (child) react during their appointment or procedure?
- Is that out of character for them?
- Is there anything that you can think of that might have caused (child) to start feeling worried about needles?
- Is there anything that they haven't been able to do because they are worried about needles?
- Do you worry about their needle fear affecting them in the future?
 - PROMPT – in what ways
- What is the impact on the family?

Parent awareness of tools to address needle fear

- Is there anything that (child) does to help them feel less worried about having a needle?
 - If yes, where did you find out about that technique?
- Is there anything that you do to try and make them feel better?
 - If yes, where did you find out about that technique?
- Do you know where you could look or go for help with (child) feeling worried about needles?

Parent thoughts on a future resource

- What do you think might help children/young people who are frightened or worried about needles?
- Is there anything that anyone could have done to make it easier for (child)?
- Is there anything that would be helpful to do at home?
- Is there anything that would be helpful at (child's) appointment?
- What should a resource for children to use at home look like? (prompt re heard copy/electronic if needed)
- Who should be able to use it?
- How should young people find out about the resource?
- Do you think parents need a tool to help their children?
- Would that be part of or separate from the child resource?
- What information would be helpful?
- Do you think parents need to understand why their child is worried?
- Do you think parents need to know how to speak to their child about it?
- How would you look for a resource to help?
- If looking online, what words would you use?
- Would you use an online resource?
- What do you think of these resources (LLTF, SCH).



- Could your child use this on their own?

Closing

- Covered everything, or is there anything else you want to discuss?
- What could healthcare professionals do to make going to the dentist easier for young people?
- What could healthcare professionals do to better support parents of young people with dental anxiety?
- Would you look at some ideas we've had from other parents and let me know what you think of them
 - Show suggested resources

Next steps

- Thank them for taking part
- Check if they have any questions about the research
- Repeat about confidentiality and anonymity
- Remind them that the findings will be published and used to create a resource for children and young people
- The findings will be shared on the website in lay language, and we can send them a copy if they would like (confirm how to send)
- Give them their thank you voucher

Appendix 8 - Your Teeth You are in Control (Living Life To The Full™) resources shown to participants during interview

YOUR TEETH YOU ARE IN CONTROL

Message to Dentist

Step 1. Let us know how you feel about going to the dentist

1) This is how worried I feel on a scale of 1 to 10 where 1 is not being scared at all.

2) These are the things I am worried about:

3) This is how painful I think it might be on a scale of 1 to 10 where 1 is not being painful at all.

4) This is what I'd like to happen:

5) This is what I don't want to happen:

6) Things I plan to do:

<input type="checkbox"/> Play music or an audiobook	<input type="checkbox"/> Play a mind game in my head
<input type="checkbox"/> Imagine somewhere great	<input type="checkbox"/> Breathe and relax
<input type="checkbox"/> Squeeze a stress ball	<input type="checkbox"/> Do some maths in my head

7) Things I want you to do:

<input type="checkbox"/> Talk to me	<input type="checkbox"/> Explain or show me what you are doing
<input type="checkbox"/> Tell me how long it will actually take	
<input type="checkbox"/> Other	-----

Step 2. Let us know what your stop signal will be

8) Agree clear stop signals.

If you want your dentist to stop, you need a way to let them know. This might be something like lifting up your left hand when you feel like a rest or you need to swallow. If you agree this with the dentist before you start treatment, it makes things much easier if you need a break.

Sometimes if your dentist is at a key point it may be important they finish off before stopping. If so, you need to agree that they give an idea of how much longer is needed. That's the time to use one of your Tools.

MY STOP SIGNAL IS: -----

Agreed by Me (sign) -----	Signed by (my dentist) -----
Date -----	Date -----

Don't forget to take this message with you to your dentist next time you go.

You can write a new message each time you visit if you want.

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YOUR TEETH YOU ARE IN CONTROL

Step 3. Let us know how your visit to the dentist went

How did it really go?

When your treatment is nearly over, here are some questions that will help you give honest feedback. Your dentist will want that – so say it as it is. Think back on your experience and how things went. There may be things to ask your dentist to do differently next time - and now's the time to ask.

Here are some phrases you could use next time you talk to your dentist.

When you did this, it made me feel:

.....

The best things that worked today were:

.....

How painful actually was it on a scale from 1 to 10 where 1 is not being painful at all?

Feedback from your dentist. Ask your dentist to write how well they thought you did here:

.....

Now, write down anything you don't want to happen again.

.....

How worried might I be next time on a scale from 1 to 10 where 1 is not being at all worried?

So, what have you learnt?

Tick the things that work for you...

- | | |
|---|---|
| <input type="checkbox"/> Having a plan | <input type="checkbox"/> Using my Tools |
| <input type="checkbox"/> Writing a Message to Dentist | <input type="checkbox"/> Taking things step by step |
| <input type="checkbox"/> Using a stop signal | <input type="checkbox"/> Asking for clear information |
| <input type="checkbox"/> Having something to look forward to afterwards | |

Other: (write in)

You've done well

It's good to recognise that with a small reward. It's your choice – but be realistic. We're not talking a holiday abroad.

A treat might be to:

- Play your favourite game for an extra hour that evening
- Watch your favourite TV programme
- Stay up a little later tonight
- Choose your next meal
- Download a new app
- Buy some music

Not sweets or fizzy drinks 😊

Choose something that will make you feel good. You deserve it.

My reward will be:

www.lttf.com/dental

Appendix 9 - 'Vaccination Fear and Anxiety' from the Sheffield Children's Hospital resource shown to participants 9-13 during interview



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Vaccination fear and anxiety

What is needle phobia?

Needle phobia is the fear of medical procedures involving needles, for example vaccinations.

Injections can cause fainting due to changes in blood pressure, and many people also have a fear of fainting. Some people feel panicky or anxious, and embarrassed by their fear but it can be overcome with support. It affects at least 1 in 10 people.

[This video explains what happens when we experience fear. \(https://www.youtube.com/watch?v=jEHwB1PG-Q&t=23s\)](https://www.youtube.com/watch?v=jEHwB1PG-Q&t=23s)

The vicious cycle of panic

When people are exposed to their phobia, it can trigger a vicious cycle of panic which may feel like it is escalating out of control.

Thoughts and feelings about the physical sensations of needles make you feel certain emotions, which then affects your behaviour and reinforces those negative thoughts and feelings.

Although this is really unpleasant, you can overcome this by breaking the cycle with a number of 'grounding techniques'. These are skills that you will need to practice.

Find a technique that suits you and practice it 3 times a day for a week, when you are not experiencing panic, so that you are used to doing it. Then you can do it when you start to experience the unpleasant thoughts, feelings and emotions.

What are grounding techniques?

Some techniques include listening to music, mindfulness and breathing techniques.

Sensory and mindfulness techniques

Use your 5 senses to help ground you and remind you of the present. [This video talks you through the following. \(https://www.youtube.com/watch?v=8lM8pgMgEs&t=22s\)](https://www.youtube.com/watch?v=8lM8pgMgEs&t=22s) Take a big, deep breath and go through this exercise.

See

Look around you and say 5 things that you can see out loud, such as "I see a bird, I see a dog, I see a house, I see a cup, I see a person."

Feel

Think of 4 things that you can feel and say them out loud. For example, "I can feel my feet are warm, I can feel my hair on my shoulders, I can feel the chair I am sitting on, I can feel my clothes on my skin."



For an accessible version or to translate, visit:
<https://tinyurl.com/2bv4foer>
Resource HVS8 | Updated 2022 | 1



Hear

Listen and say 3 things that you can hear. For example, "I can hear a dog barking, I can hear an aeroplane, I can hear people talking."

Smell

Have a think about 2 things that you can smell and say them out loud. If you cannot smell anything, you can move to a different spot, or just think and imagine your favourite smells, like pizza cooking, and clean clothes.

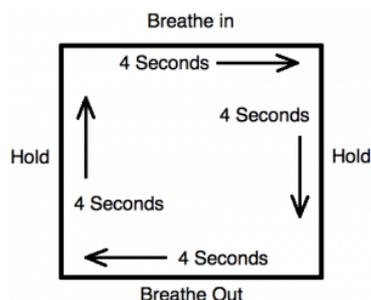
Taste

Say 1 thing you can taste, such as toothpaste your favourite sweets. If you cannot taste anything, then think of something you like the taste of.

Breathing exercises

Follow along the square in your head or use your finger to trace along the lines. Breathe in for 4 seconds, then hold for 4 seconds, then breathe out for 4 seconds, and hold for 4 seconds. Keep going around the circle until you feel in control of your breathing again.

You can shorten or lengthen the timings if 4 seconds is a bit too long or short for you. This video talks you through the exercise.



What can help me overcome this fear?

Practice your grounding technique 3 times a day for a week leading up to the event you fear, such as injection or blood test. Use it immediately before, during and after, if needed.

Consider where and how you will feel most comfortable and tell the staff that you feel anxious. You could even mention the technique you have practiced to help you.

Consider having someone with you who you trust.

Work through the resources including the Fear Ladder worksheet.



For an accessible version or to translate, visit:
<https://tinyurl.com/2bv4foer>
Resource HVS8 | Updated 2022 | 2



Fear Ladder

Please download and print off the [Fear Ladder worksheet \(https://library.sheffieldchildrens.nhs.uk/wp-content/uploads/2022/05/Fear-Ladder-worksheet.pdf\)](https://library.sheffieldchildrens.nhs.uk/wp-content/uploads/2022/05/Fear-Ladder-worksheet.pdf).

Put the easiest things you can achieve at the bottom. Tackle them step by step and slowly become more confident. Practise sitting with your thoughts and feelings at each stage and use your grounding techniques. Over time and with practise you will become more comfortable with your fear.

Contact us

If you have any questions or concerns, please contact us, on 0114 305 3230 Monday to Friday between 8.30am and 4pm.

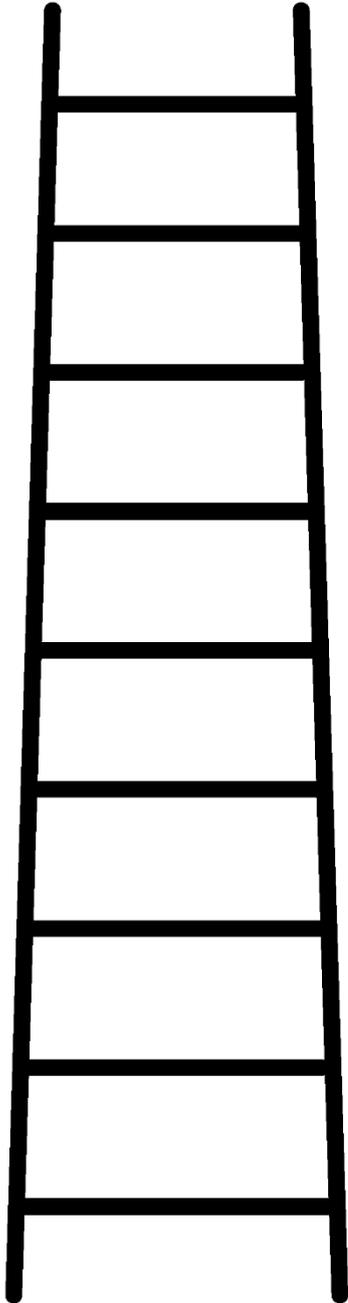
Disclaimer

Please note: this is a generic information sheet relating to care at Sheffield Children's NHS FT. These details may not reflect treatment at other hospitals. This information is not intended as a substitute for professional medical care. Always follow your healthcare professionals' instructions. If this resource relates to medicines, please read it alongside the medicine manufacturer's patient information leaflet. If this information has been translated into another language from English, efforts have been made to maintain accuracy, but there may still be some translation errors. If you are unsure about any of the guidance in this resource or have specific questions about how it relates to your child, always ask your healthcare professional for further advice.



For an accessible version or to translate, visit:
<https://tinyurl.com/2bv4foer>
Resource HVS8 | Updated 2022 | 3

The fear that I am facing is _____



Situation

Anxiety 0-10

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____



Fear Ladder worksheet

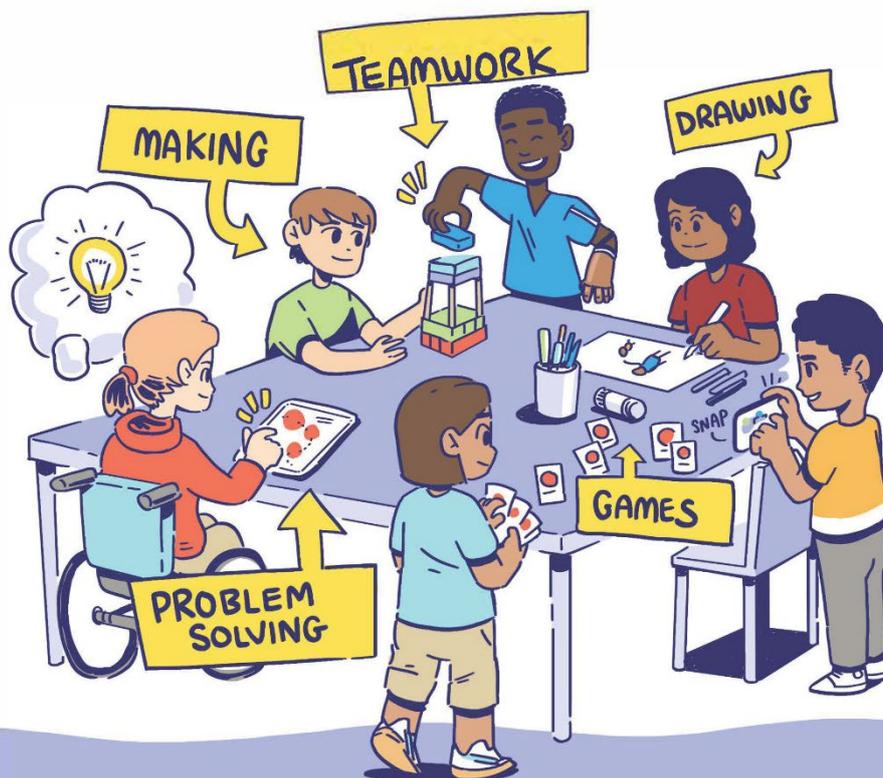


**Appendix 10 - Recruitment poster for co-design collaborators
(original) Children and Young people**



If you are aged between 11 - 16 we'd like to invite you to a creative and fun workshop.

At this workshop we're going to work together to find ways to help young people who are afraid of needles.



If you want to join in, just send an email to:

f.sotir@sheffield.ac.uk

and tell her you saw this poster!

**Appendix 11 - Recruitment poster for co-design collaborators
(original) – healthcare professionals**



If you are a healthcare professional who undertakes **needle-based procedures with children , we'd like to invite you to take part in some creative workshops.**

At these workshops, we're going to work together to find ways to help young people who are afraid of needles.



If you're interested and want to know more, just send an email to:

f.sotir@sheffield.ac.uk

and tell her you saw this poster!

Appendix 12 - Recruitment poster for co-design collaborators (amended)



Image:Freepik.com

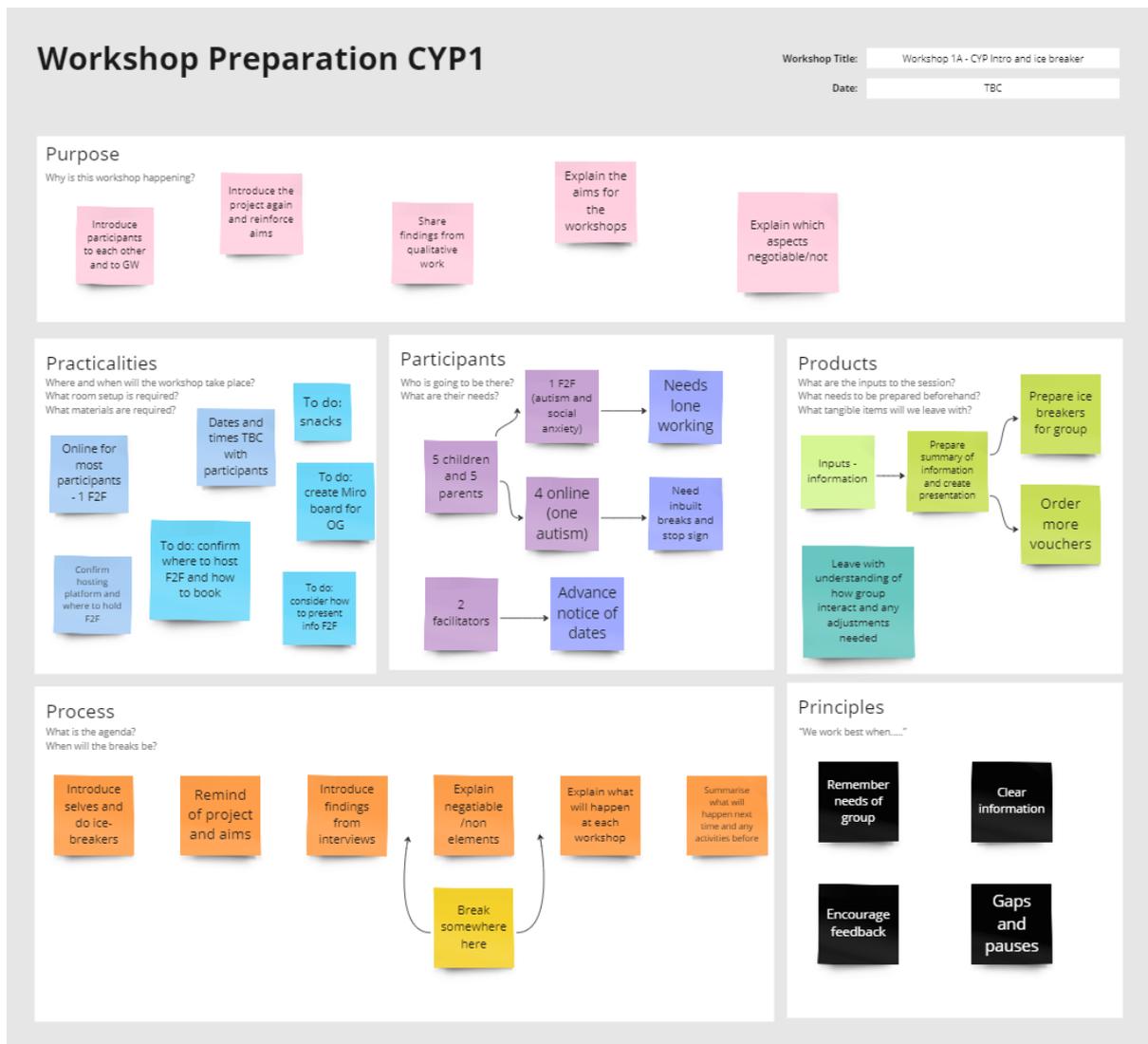
If you are aged between 11-16, we'd like to invite you to some creative and fun online workshops!

At these workshops, we're going to work together to create resources to help young people who are afraid of needles.

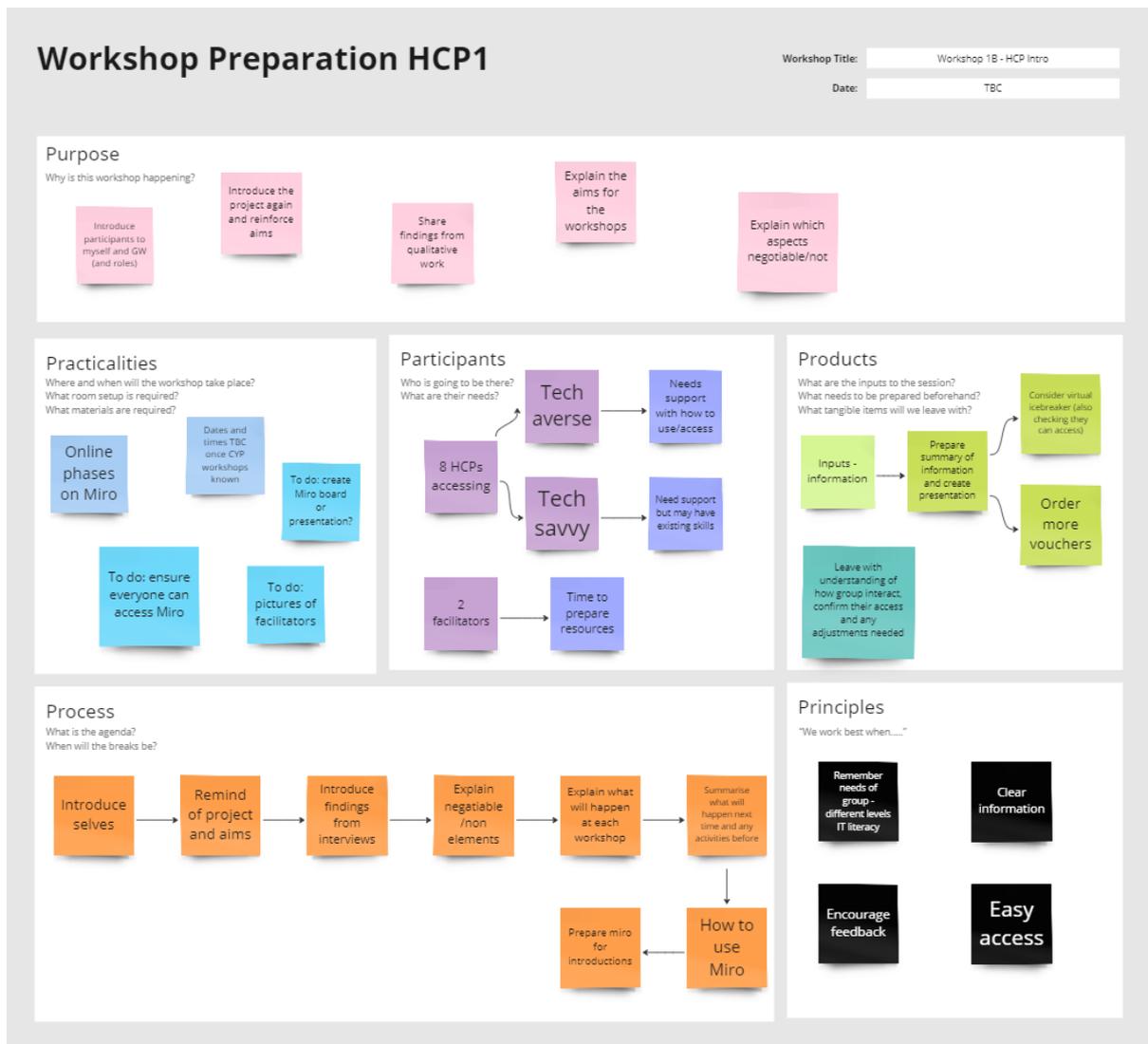
If you might want to join in, just send an email to:

f.sotir@sheffield.ac.uk

Appendix 13 - Example planning board for Workshop 1 – Children, Young people and Parents/Carers



Appendix 14 - Example planning board for Phase 1 – Healthcare professionals



Appendix 15 - Introduction slides for Workshop 1A

Frame 1

Best part of your day today

WELCOME!

Gertrude

Fiona

Martha

Thomas

Getting to know each other

Maria

Miranda

Patricia

Rosie & Peppa

Frame 2

OUR PROJECT



The illustration shows a line of ten diverse people of various ages and ethnicities. From left to right: a man in a yellow shirt covering his ears, a man in a yellow shirt with a distressed expression, a young girl in a white dress with her arms crossed, a woman in a blue top with her hand to her chest, a woman in an orange top with her arms crossed, a young girl in a green jacket crying, a man in an orange shirt with his hands to his face, a man in a white shirt hugging his knees, and a man in a blue shirt with his arms raised in a celebratory gesture. A small purple character is visible in the bottom left corner of the frame.

Frame 3

PLAN FOR TODAY



EXPLAIN WHAT WE'VE LEARNED SO FAR



***TALK ABOUT WHAT WILL HAPPEN IN OUR
WORKSHOPS***



TALK ABOUT WHAT WE WILL BE DOING NEXT TIME



Frame 4

WHAT HAVE WE LEARNED ALREADY?



Frame 5

SUMMARY OF FINDINGS SO FAR

Does anything the young people said surprise you?



Some of us find treatment with needles hard

It can make us experience physical symptoms



It can make it difficult for us to have the treatment we need

Thinking about needles can make us anxious



Frame 6

SUMMARY OF FINDINGS SO FAR

Is there anything here you agree with?



Most of us look for information online

We want information about our procedures



We want ideas of how to cope when we have treatment with needles

We want illustrations, not pictures of real people



Frame 7

SUMMARY OF FINDINGS SO FAR



We want more visual information

We want to be able to use the resource on a computer or phone



We want to communicate with the people treating us

We want to be able to use a resource by ourselves



Is there anything you think is missing?

Frame 8

SUMMARY OF FINDINGS SO FAR



We want to help our children

We want to be able to use the resource on AND offline



We want to have our own section and access to the child section

We want visual AND written information



Does anything the parents said surprise you?

Is there anything you think is missing?

ALREADY DECIDED

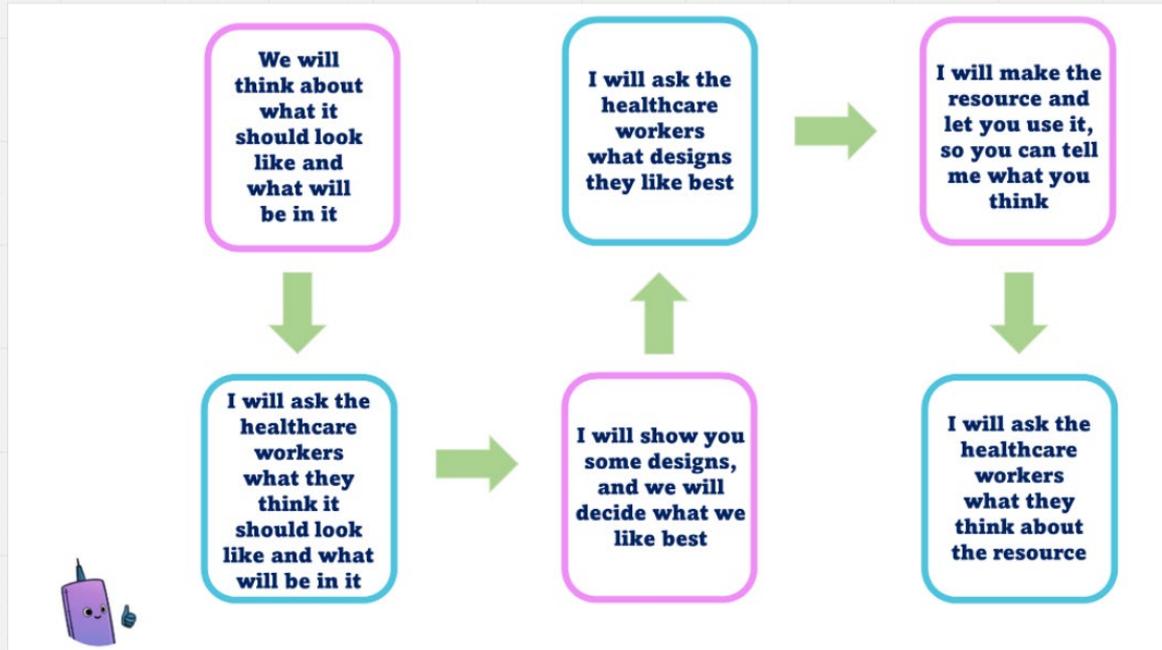
- It will be online, but you will be able to print it off**
- It will have information about needles, and ideas of how to feel better**
- There will be a bit for young people and a separate bit for parents**
- There will be a way for young people to write to healthcare workers about their worries**



WHAT DO WE NEED TO DECIDE?

- What should the resource have in it?**
- What should it look like?**
- How will people find it?**
- How will the communication tool work?**



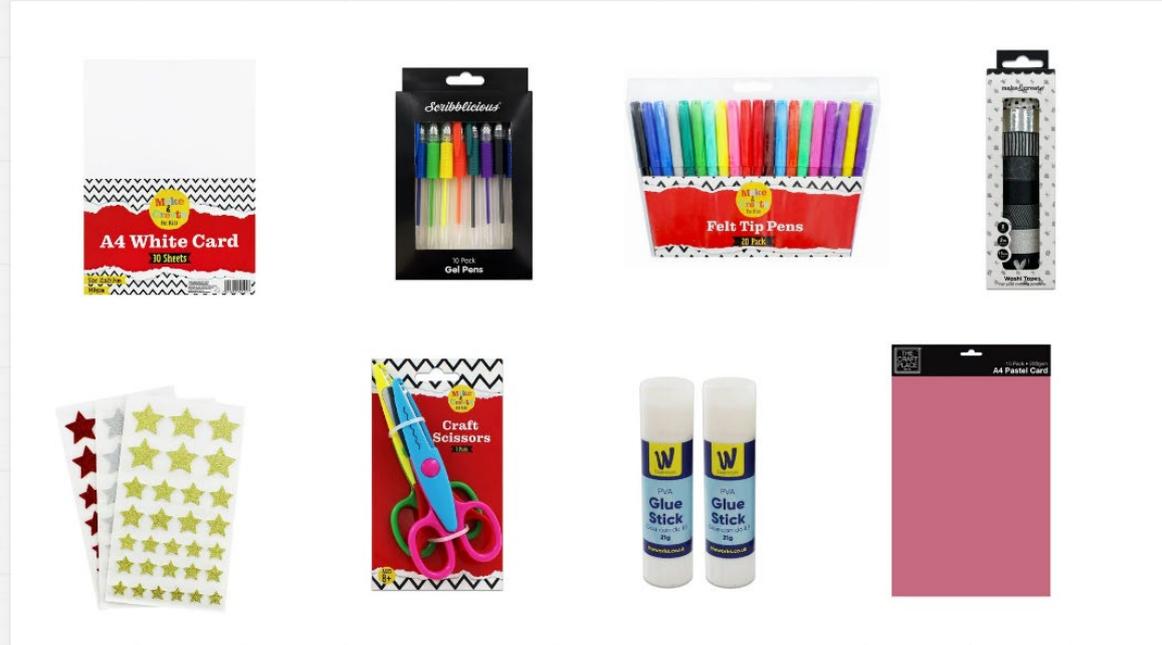


NEXT TIME!

- 1 I will ask you to do an activity at home**
- 2 I want you to think about how it will LOOK**
- 3 When you are finished, send me a photo!**
- 4 We will look at these together next time**



Frame 14



Frame 15





FIONA

f.sotir@sheffield.ac.uk

NEXT WORKSHOP

19TH OCTOBER 6.30PM



Appendix 16 - Rosie and Gertrude's mood boards from Workshop 2A
Gertrude's board



Rosie's board



Appendix 17 – Parent advice sheet designs from Workshop 3A

Improve your child's experience

How can you help your child during medical Procedures?

How can you act?
What can you say?

Try saying

C ✓ What can we do to help you through the Procedure. (look at the cards) invites Participation

Ash ✓ your getting the Procedure to help you healthy we can ask the clinician/dentist what when & how they are doing - what do you want to know

M ✓ your having a needle Procedure. (neutral language)

✓ What do you want to be doing during the Procedure? (address concerns)

my ✗ Positive Behaviour.

The language correct

Avoid / instead.

✗ you will be on dismissive wording to worry about - dismissive and vague. (does not invite Child Participation)

✗ It's just something you need doing come on lets get it done. stop asking questions.

✗ you are getting a needle jab, it might be sharp / painful (fear inducing language)

✗ Don't worry dismisses concerns.

Keep listening to your child

calm

PARENTS

HAVE A CHAT AS SOON AS YOU FIND OUT ABOUT PROCEDURE, LET YOUR CHILD TO THINK ABOUT:

- WHAT WOULD YOU LIKE TO ASK
- WHAT WOULD YOU LIKE TO DO TO RELAX?
- FUN PART - WHAT WOULD YOU LIKE TO DO AFTER?

TRY TO PUT YOURSELF IN YOUR CHILD'S SHOES. THINK ABOUT THINGS THAT MAKE YOU ANXIOUS, AND HOW YOU ARE FEELING THEM, AND WHAT YOU ARE DOING TO HELP YOURSELF

DO NOT SHOW OR TELL YOUR CHILD THAT YOU ARE WORRIED, BECAUSE THEY WILL BE WORRIED, TOO.

STAY CALM AND SMILE.

AFTER APPOINTMENT

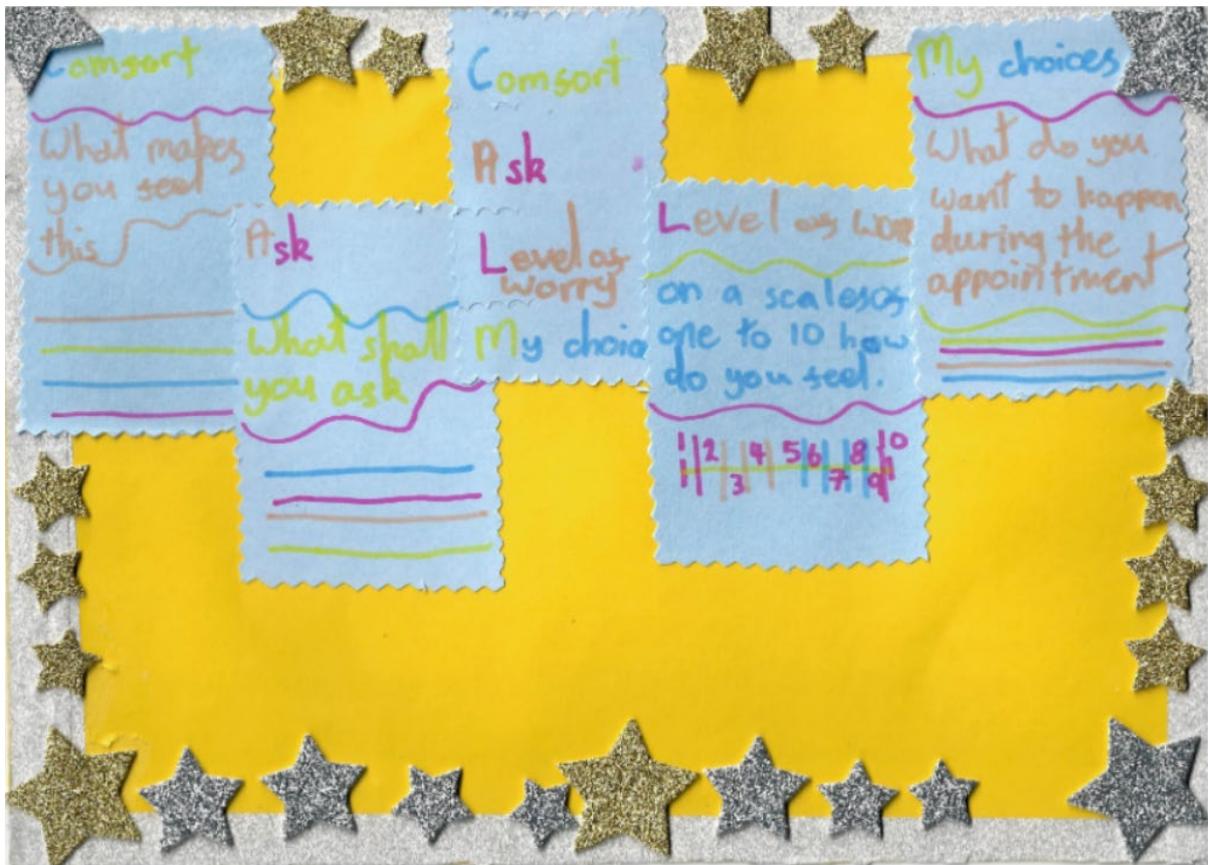
DON'T SAY - THAT WASN'T TOO HARD, WASN'T IT?

SAY - SO HOW WAS IT? HOW DID YOU FEEL?

WHAT HAS HELPED YOU?

JUST HAVE A NICE, RELAXED CHAT, NOT AN INTERVIEW.

Appendix 18 - Rosie's communication tool design from Workshop 3A (voted favourite)



Appendix 19 - Reflective packs
Young People



Contents

What is in the workbook?

Thank you for helping me with this project - I really appreciate all the time and effort you've put in to help me make a resource for young people to feel better about needles.

I would like you to use the resource now and think about the things you like, or don't like, as well as any ideas for ways we can make it better in the future. The activities in this workbook might help you to think about the resource in different ways. You can use the workbook to take notes, so you can remember your thoughts and ideas when we chat about it in our workshop.

You can do as many or as few of the activities as you want to, and if you have extra thoughts, please let me know!

The activities :

Page 3 – Activity 1 First impressions

Page 4 – Activity 2 Using the resource

Page 5 – Activity 3 Your experience and thoughts

Page 6 – Activity 4 The communication tool

Page 7 – Activity 5 The resource overall

Page 8 – Extra space Extra thoughts

You will be sent a link to access the resource to your Mum's email address.

Activity 1

First impressions

When you click the link and see the welcome page for the first time – what do you think?

You can make notes in the boxes below.

You might want to think about:

- ★ Layout – is it clear and easy to see what you need to click next?
- ★ Design – does it look nice? Is it a welcoming design?
- ★ Pictures – what do you think about the images on this page?
- ★ Font – can you read everything clearly?

Good points

Bad points

General points

Activity 2

Using the resource

Have a go at looking at different parts of the resource – see if you can find:

One example of a procedure/treatment

One idea to feel better

The real-life story

You can make notes in the boxes below. You might want to think about:

- ★ How easy was it to find what you were looking for?
- ★ Was there anything that didn't work?
- ★ Did you understand everything in the parts you chose to look at?
- ★ What did you like/not like so far?

Good points

Bad points

General points

Activity 3

Your experience and thoughts

Take some time to look over the different parts of the resource. Once you've had time to have a good look, I have some specific questions you can answer below.

1. While you were using the resource, was there anything that didn't work?
2. Was there anything that you didn't understand?
3. Is there anything you think I should add?

What is your favourite part of the resource?

If you could change one thing about the resource, what would it be?

Do you have any other comments?

Activity 4

The communication tool

I've given you a print-out of the communication tool we designed together. I'd like you to have a go at using it – fill it in and cut it out. How did it go?

You can make notes in the boxes below.

You might want to think about:

- ★ Did you have enough space to write?
- ★ Could you understand what to write in each box?
- ★ Was it easy to cut out and fold?
- ★ Was there anything you wanted to write but didn't know which part to use?

Good points

Bad points

General points

Activity 5

The resource overall

Now you've had a chance to look at and use the resource, I'd like to know what you think of it overall.

Please put a star or a mark beside the words below that you think describe our resource.



Can you think of any others? Write them here!

Empty rounded rectangular box for writing additional adjectives.

Activity 6

Who is this resource for?

I would like you to think about who this resource would work for. Please put a star or mark if you think these people would find our resource helpful:

People younger than 6

People aged 6 – 11 years old

People aged 12 – 16 years old

People aged 16 – 19 years old

Girls

Boys

Non – binary

People who speak English as a second language

People who find reading hard

People who are only a little worried about needles

People who are quite worried about needles

People who are very worried about needles

People who don't have a computer

People who do have a computer

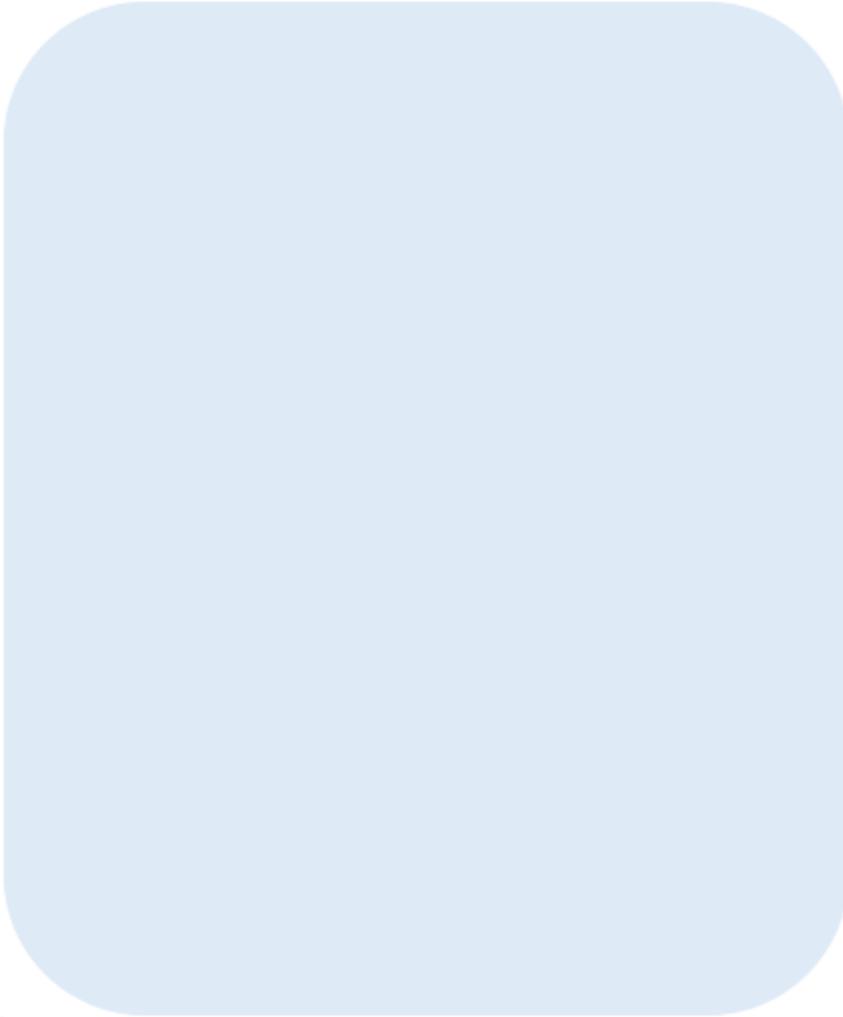
Adults who look after a young person with worries about needles

Can you think of any other people that might find it helpful? Write them here!

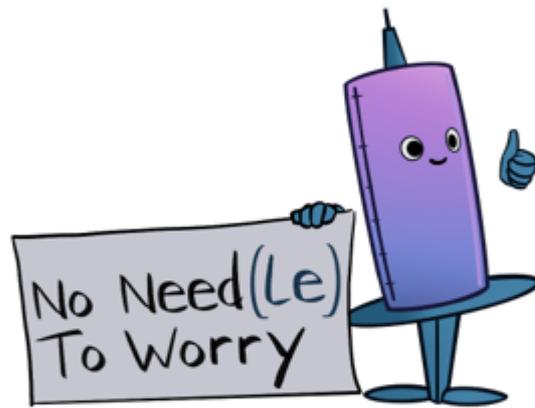
Activity 7

Any extra thoughts

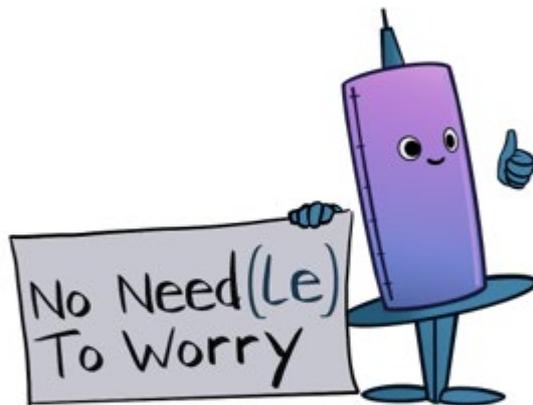
If there is anything else you want to tell me about the resource, you can write about it here!



Thank You!



**Welcome to
your
Activity Pack!**



**This pack is for
MARTHA**

Contents

What is in the workbook?

Thank you for helping me with this project - I really appreciate all the time and effort you've put in to help me make a resource for young people to feel better about needles.

I would like you to use the resource now and think about the things you like, or don't like, as well as any ideas for ways we can make it better in the future. The activities in this workbook might help you to think about the resource in different ways. You can use the workbook to take notes, so you can remember your thoughts and ideas when we chat about it in our workshop.

You can do as many or as few of the activities as you want to, and if you have extra thoughts, please let me know!

The activities:

Page 3 – Activity 1 First impressions

Page 4 – Activity 2 Using the resource

Page 5 – Activity 3 Your experience and thoughts

Page 6 – Activity 4 The communication tool

Page 7 – Activity 5 The resource overall

Page 8 – Extra space Extra thoughts

You will be sent a link to access the resource to your email address.

Activity 1

First impressions

When you click the link and see the welcome page for the first time – what do you think?

You can make notes in the boxes below.

You might want to think about:

- ★ Layout – is it clear and easy to see what you need to click next?
- ★ Design – does it look nice? Is it a welcoming design?
- ★ Pictures – what do you think about the images on this page?
- ★ Font – can you read everything clearly?

Good points

Bad points

General points

Activity 2

Using the resource

Have a go at looking at different parts of the resource – see if you can find:

The parent section.

Ideas for how to have conversations. |

Ideas for how to feel better.

You can make notes in the boxes below. You might want to think about:

- ★ How easy was it to find what you were looking for?
- ★ Was there anything that didn't work?
- ★ Did you understand everything in the parts you chose to look at?
- ★ What did you like/not like so far?

Good points

Bad points

General points

Activity 3

Your experience and thoughts

Take some time to look over the different parts of the resource. Once you've had time to have a good look, I have some specific questions you can answer below.

1. While you were using the resource, was there anything that didn't work?
2. Was there anything that you didn't understand?
3. Is there anything you think I should add?

What is your favourite part of the resource?

If you could change one thing about the resource, what would it be?

Do you have any other comments?

Activity 4

The Parent's Advice sheets

I've given you a print-out of the parent advice sheets we designed together. I'd like you to read them and tell me what you think.

You can make notes in the boxes below.

You might want to think about:

- ★ Was the advice appropriate?
- ★ Did all of the advice make sense?
- ★ Is there anything missing?
- ★ Did you understand how to use the communication tool with your child?

Good points

Bad points

General points

Activity 5

The resource overall

Now you've had a chance to look at and use the resource, I'd like to know what you think of it overall.

Please put a star or a mark beside the words below that you think describe our resource.



Can you think of any others? Write them here!

Empty rounded rectangular box for writing additional adjectives.

Activity 6

Who is this resource for?

I would like you to think about who this resource would work for. Please put a star or mark if you think these people would find our resource helpful:

People younger than 6

People aged 6 – 11 years old

People aged 12 – 16 years old

People aged 16 – 19 years old

Girls

Boys

Non – binary

People who speak English as a second language

People who find reading hard

People who are only a little worried about needles

People who are quite worried about needles

People who are very worried about needles

People who don't have a computer

People who do have a computer

Adults who look after a young person with worries about needles

Can you think of any other people that might find it helpful? Write them here!

Activity 7

Any extra thoughts

If there is anything else you want to tell me about the resource, you can write about it here!



Welcome to
your
Activity Pack!



This pack is for
PERCY

Contents

What is in the workbook?

Thank you for helping me with this project - I really appreciate all the time and effort you've put in to help me make a resource for young people to feel better about needles.

I would like you to use the resource now and think about the things you like, or don't like, as well as any ideas for ways we can make it better in the future. The activities in this workbook might help you to think about the resource in different ways. You can use the workbook to take notes if you would like, so you can record your thoughts and ideas.

You can do as many or as few of the activities as you want to, and if you have extra thoughts, please let me know.

The activities:

Page 3 – Activity 1 First impressions

Page 4 – Activity 2 Using the resource

Page 5 – Activity 3 Your experience and thoughts

Page 6 – Activity 4 The communication tool

Page 7 – Activity 5 The resource overall

Page 8 – Extra space Extra thoughts

You will be sent a link to access the resource to your email address.

Activity 1

First impressions

When you click the link and see the welcome page for the first time – what do you think?

You can make notes in the boxes below.

You might want to think about:

- ★ Layout – is it clear and easy to see what you need to click next?
- ★ Design – does it look nice? Is it a welcoming design?
- ★ Pictures – what do you think about the images on this page?
- ★ Font – can you read everything clearly?

Good points

Bad points

General points

Activity 2

Using the resource

Have a go at looking at different parts of the resource – as a challenge, see if you can find:

Information about why young people feel worried.

Ideas for how to have conversations for parents.

The communication tool

You can make notes in the boxes below. You might want to think about:

- ★ How easy was it to find what you were looking for?
- ★ Was there anything that didn't work?
- ★ Did you understand everything in the parts you chose to look at?
- ★ What did you like/not like so far?

Good points

Bad points

General points

Activity 3

Your experience and thoughts

Take some time to look over the different parts of the resource. Once you've had time to have a good look, I have some specific questions you can answer below.

1. While you were using the resource, was there anything that didn't work?
2. Was there anything that you didn't understand?
3. Is there anything you think I should add?

What is your favourite part of the resource?

If you could change one thing about the resource, what would it be?

Do you have any other comments?

Activity 4

The Parent Advice sheets and Communication Tool

I would like you to now focus on the communication tool and the parent advice sheets. I'd like you to look at them and tell me what you think.

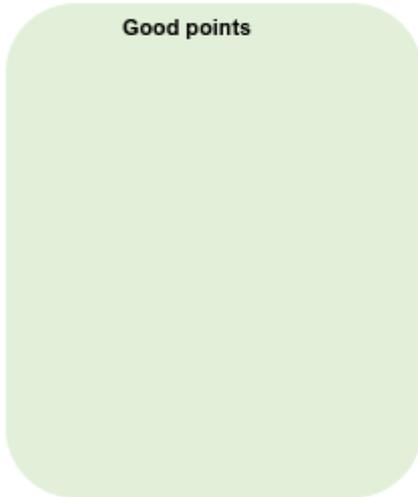
You can make notes in the boxes below.

The parent advice sheets.

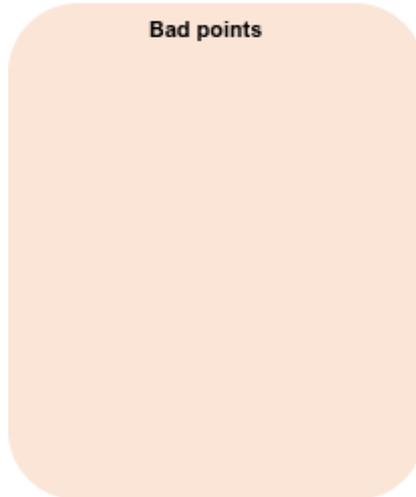
You might want to think about:

- ★ Was the advice appropriate?
- ★ Did all of the advice make sense?
- ★ Do you think the advice given to parents would help you as a healthcare professional (would it improve the appointment experience?)
- ★ Is there anything missing?

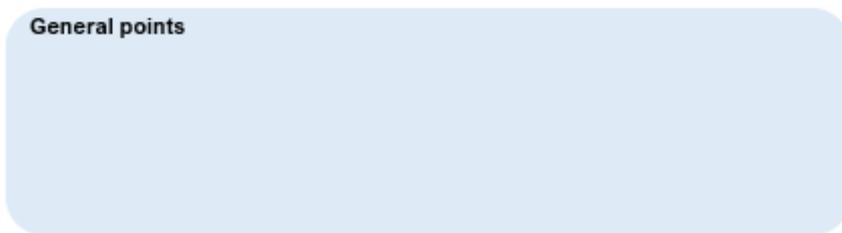
Good points



Bad points



General points



The communication tool

You might want to think about:

- ★ Is there enough have enough space for young people to write?
- ★ Could you understand what they would write in each box?
- ★ Would you be able to read this quickly if a young person gave it to you?
- ★ Is there anything you think is missing?

Good points

Bad points

General points

Activity 5

The resource overall

Now you've had a chance to look at and use the resource, I'd like to know what you think of it overall.

Please put a star or a mark beside the words below that you think describe our resource.



Can you think of any others? Write them here!

A large, light blue rounded rectangular box for writing additional adjectives.

Activity 6

Who is this resource for?

I would like you to think about who this resource would work for. Please put a star or mark if you think these people would find our resource helpful:



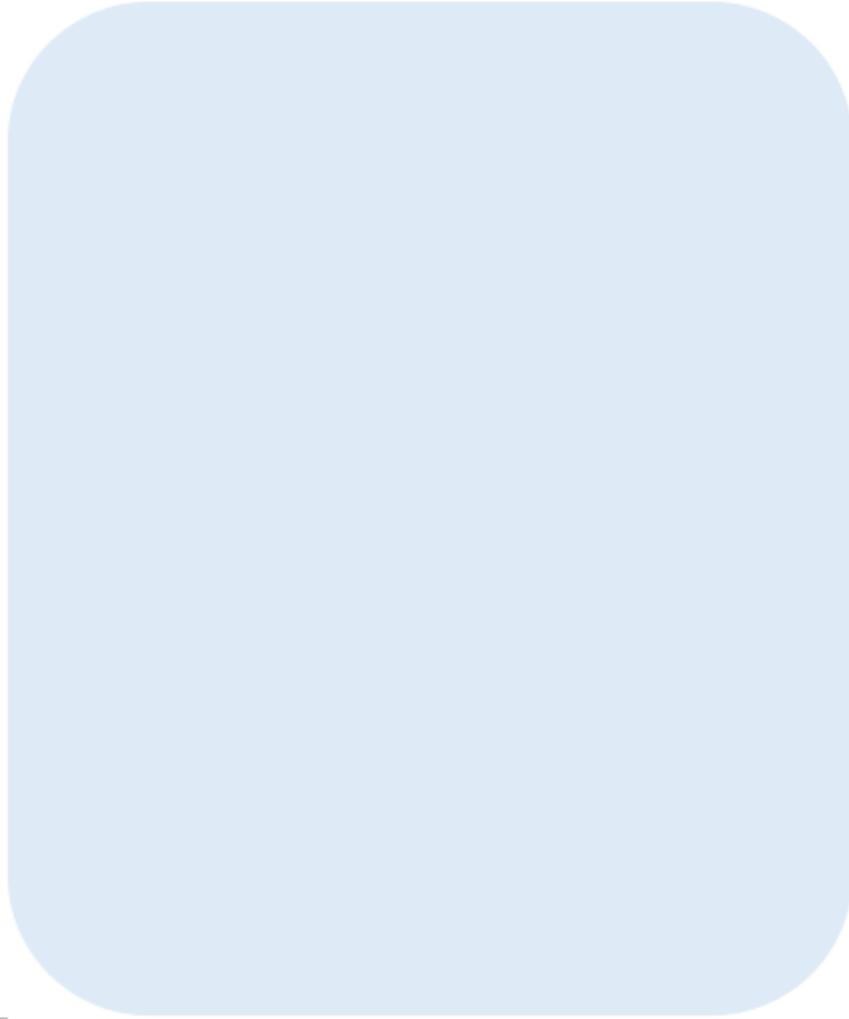
- People younger than 6
- People aged 6 – 11 years old
- People aged 12 – 16 years old
- People aged 16 – 19 years old
- Girls
- Boys
- Non – binary
- People who speak English as a second language
- People who find reading hard
- People who are only a little worried about needles
- People who are quite worried about needles
- People who are very worried about needles
- People who don't have a computer
- People who do have a computer
- Adults who look after a young person with worries about needles

Can you think of any other people that might find it helpful? Write them here!

Activity 7

Any extra thoughts

If there is anything else you want to tell me about the resource, you can write about it here!



Appendix 20 – Cover letter sent to Headteachers



Mrs Fiona Sotir
Office C07
School of Clinical Dentistry
University of Sheffield
10 Claremont Crescent
Sheffield
S10 2TA

f.sotir@sheffield.ac.uk

HEADTEACHER NAME

SCHOOL ADDRESS

POSTCODE

DATE

|

No Need(le) To Worry
Ethics Approval Reference: 22/PR/1451

Dear Headteacher,

I am writing to you to ask about the possibility of undertaking some research with students at your school this academic year. I am a Research Fellow at the University of Sheffield, supervised by Professor Zoe Marshman (Professor of Dental Public Health) and my project is funded by the research arm of the NHS – the National Institute for Health and Care Research. I have developed a self-help resource which I hope will help young people aged 11-16 years old feel better about having treatment involving needles.

I would really like to include young people having scheduled vaccinations as part of the project. It would involve 20 young people in total, who are due to have a vaccination this year. It would involve a small assembly with all the young people who are due to have the vaccination, where I would tell them about the study and provide them with information packs. If they wished to take part, they would complete the study forms at home and hand them back to an appropriate area in the school (such as the office) where I would collect them at a convenient time.

The young people who take part will be given access to the resource before their scheduled vaccination, and access to a communication tool which they may choose to share with the nurse who delivers their vaccine on the day.

By taking part your school would be contributing to research that will hopefully reduce needle fear in this age group through a nationally available resource.

Invitation to Headteacher Letter V1.0 (03.08.2023)
STH 20994

The commitment from the school would be:

1. To allow me to provide a short 10-minute presentation to the students about the study (I would be happy to provide this as a standalone presentation, or to tie-in with an existing information sessions or assembly). Students would be provided with information packs at this session.
2. To allocate a space for any interested students to return their forms.
3. To allow me to access the school to collect completed forms.

I have an enhanced DBS check, as does the research nurse who may accompany me during the presentation.

The University of Sheffield adheres to strict procedures on conducting ethical research with children and young people. Before any research would begin, I would complete the information session with students, and they will be provided with information sheets for their parent/carer and asked to read through these and complete enclosed consent forms only if they wish to participate. The students will be made aware that they do not have to take part, and their vaccination programme will not be affected if they decline. If they choose to take part, they can also withdraw at any time without needing to explain why.

I will clearly explain that only 20 students will be selected to take part. In the instance that there is a surplus of students who are eligible and interested, those who are not selected to take part will still be offered access to the resource. I will contact students directly through their nominated contact details to advise whether or not they have been selected for participation. I have attached a copy of the information sheets which would be provided to young people and their parent/carer.

All participants, and the school, will be made anonymous in all research reports. All data collected will be kept in strict confidence, available only to myself and my supervisor, and not used other than specified without the express further consent of all involved.

If your school would like to take part in the study, or you need more information about what is involved, please contact me at f.sotir@sheffield.ac.uk. I would be delighted to arrange a meeting or to provide further details in person or by email.

Thank you for your time and attention. I look forward to hearing from you.

Yours Sincerely,



Fiona Sotir
Doctoral Research Fellow
University of Sheffield

Appendix 21 - Baseline questionnaire Stage Two quantitative element



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Research team to complete	
Site ID:	<input type="text"/>
Participant ID:	<input type="text"/>

No Need(le) To Worry: helping to make having needles easier for children and teenagers

Young Person First Questionnaire Healthcare

Instructions

Thank you for taking place in the project. We would like you to:

- ☺ Answer the questions
- ☺ Remember there are no right or wrong answers! We just want to know how you feel
- ☺ Give this booklet back to the person who gave it to you



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The first questions are about how you feel about needles

1. Have you ever had treatment with a needle before?

Yes

No

If you answered 'Yes', please tick which of these you have had before:

Treatment	Had it before?
Vaccinations (e.g. an injection of medicine to stop you from getting sick/poorly)	<input type="checkbox"/>
Getting an intravenous injection (e.g. a needle in your vein that connects to tubes and a bag of medicine)	<input type="checkbox"/>
Having a blood test (e.g. a needle in your vein and blood withdrawn)	<input type="checkbox"/>
Having a numbing injection at the dentist	<input type="checkbox"/>
Giving a blood sample by having your finger pricked	<input type="checkbox"/>



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2. How do you feel when you need to have a needle? Please circle one of the faces below:



3. How do you feel when you need to have a needle? Place a mark along this line to show how you feel



Not at all worried

Extremely worried



4. Below are a number of statements that young people use to describe their worry about having needles and injections.

Read each carefully and tick the number that best describes your worry.

There are no right or wrong answers.

Please answer all items.

How worried would you feel about:

Statement	0 Not worried	1 A little bit worried	2 Somewhat worried	3 Very worried	4 Extremely worried
Giving a blood sample by having your finger pricked	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Having a needle in your arm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Looking at a picture of a needle	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The smell of a hospital	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Having a numbing injection at the dentist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Having a blood test (e.g. a needle in your vein and blood withdrawn)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Watching another person have a blood test	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Getting an injection in your bottom	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Looking at a picture of a person having a needle	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Young Person Baseline Questionnaire Health V1.0 (11.10.2022)

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How worried would you feel about:

Statement	0 Not worried	1 A little bit worried	2 Somewhat worried	3 Very worried	4 Extremely worried
Listening to someone talking about injections	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Looking at and touching the veins in your arm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Watching a video about a person getting a needle	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Watching another person getting a needle	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Watching a person in a nurse uniform	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Having your ears pierced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Getting a vaccination (e.g. an injection of medicine to stop you from getting sick/poorly)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Getting an intravenous injection (e.g. a needle in your vein that connects to tubes and a bag of medicine)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Watching another person having their finger pricked	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



These questions are all about you, please complete or tick the boxes

5. What is your postcode?

--	--	--	--	--	--	--

6. Choose one section from A to F and tick the box that best describes your ethnic group

A – White	Welsh/ English/ Scottish/ Northern Irish/ British	<input type="checkbox"/>
	Irish	<input type="checkbox"/>
	Gypsy or Irish Traveller	<input type="checkbox"/>
	Any other White background (please write in the box)	
B – Mixed	White and Black Caribbean	<input type="checkbox"/>
	White and Black African	<input type="checkbox"/>
	White and Asian	<input type="checkbox"/>
	Any other Mixed background (please write in the box)	
C – Asian	Indian	<input type="checkbox"/>
	Bangladeshi	<input type="checkbox"/>
	Pakistani	<input type="checkbox"/>
	Chinese	<input type="checkbox"/>
	Any other Asian background (please write in the box)	
D – Black	Black Caribbean	<input type="checkbox"/>
	Black African	<input type="checkbox"/>
	Any other Black background (please write in the box)	
E – Other	Arab	<input type="checkbox"/>
	Any other background (please write in the box)	
F – Prefer not to say	Prefer not to say	<input type="checkbox"/>

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7. Which of these best describes your gender?

Female/Girl

Male/Boy

Prefer not to say

Other (please write) _____

Thank you very much for your time

Appendix 22 - Follow-up questionnaire Stage Two quantitative element



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Research team to complete	
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Participant ID:	<input type="text"/>

No Need(le) To Worry: helping to make having needles easier for children and teenagers

Young Person Second Questionnaire Healthcare

Instructions

Thank you for taking place in the project. We would like you to:

- ☺ Answer the questions

- ☺ Remember there are no right or wrong answers! We just want to know how you feel

- ☺ Give this booklet back to the person who gave it to you

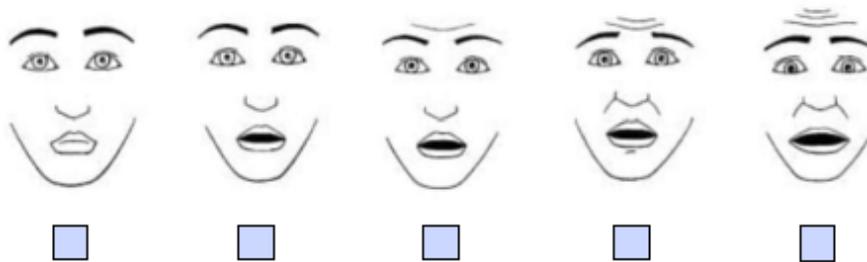


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1. How do you feel about having a needle today? Please circle one of the faces below:



2. How do you feel about having a needle today? Place a mark along this line to show how you feel



Not at all worried

Extremely worried



3. Below are a number of statements that young people use to describe their worry about having needles and injections.

Read each carefully and tick the number that best describes your worry.

There are no right or wrong answers.

Please answer all items.

How worried would you feel about:

Statement	0 Not worried	1 A little bit worried	2 Somewhat worried	3 Very worried	4 Extremely worried
Giving a blood sample by having your finger pricked	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Having a needle in your arm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Looking at a picture of a needle	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
The smell of a hospital	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Having a numbing injection at the dentist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Having a blood test (e.g. a needle in your vein and blood withdrawn)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Watching another person have a blood test	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Getting an injection in your bottom	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Looking at a picture of a person having a needle	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



How worried would you feel about:

Statement	0 Not worried	1 A little bit worried	2 Somewhat worried	3 Very worried	4 Extremely worried
Listening to someone talking about injections	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Looking at and touching the veins in your arm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Watching a video about a person getting a needle	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Watching another person getting a needle	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Watching a person in a nurse uniform	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Having your ears pierced	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Getting a vaccination (e.g. an injection of medicine to stop you from getting sick/poorly)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Getting an intravenous injection (e.g. a needle in your vein that connects to tubes and a bag of medicine)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Watching another person having their finger pricked	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Appendix 23 - Topic Guide for Stage Two Qualitative Interviews Children and Young people



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No Need(le) To Worry: Development and feasibility study of a self-help cognitive behavioural therapy resource for childhood needle fear

Topic Guide – Child/Young person Stage 2 interviews

Introduction

Purpose is to talk to young people about their experiences of using the needle fear resources at home before their recent treatment.

Key information

- Introduce self and re-explain the project (who it is for, what it is about)
- The interview will last as long as you like, probably around 30 minutes
- We will be recording what we are saying today
- This is not a test, and there are no right or wrong answers
- You don't have to talk about anything you don't want to
- You can choose a different name for us to use on the recording so we don't use your real name
- Anything we use from this interview will not be linked to your real name and we won't tell anyone else what you say
- If you change your mind about taking part, or want a break just let me know and we will stop
- At the end of the interview I will give you a voucher to say thank you for your time
- If you say anything that makes me really worried about you then I might need to speak with your parent/carer or another adult to make sure you are alright and get you any help you need
- What would you like me to call this (show resource) and then use term
- Do you have any questions before we start?



Background

- Could you tell me a bit about yourself (favourite subject at school, free time when not busy with school work)
- How do you normally feel when you have treatment with a needle (PROMPTS: for vaccinations, dental injections, blood tests as examples)?
- What makes you feel anxious/worried or afraid about needles?
- What was the treatment you had after using the resource?

Acceptability of resource

- How did you find using the resources – take through specific elements
- Would you recommend the resources to friends who might be worried?
- What did you like about using them?
- What did you not like about using them?
- Could you tell me a little bit about which bits you found easy to use and which bits you found more difficult to use (if any)?
- What did you think about the resources given to your parent/carer?
- Please could you say a little bit about whether you would like to use the resources again in future?
- Are they something you would actually plan to use again?
 - Are there any things which would mean you are more likely to use it again?
 - Are there any things that you think would prevent you from using it?

Perceived effectiveness

- Do you feel using these extra things helped you feel less worried or anxious about needles?
 - If yes - in what ways do you think it made you feel less anxious/worried?
 - If no – why don't you feel it helped you?
- Could you say a bit about whether you think using the resource changed your experience of having your treatment?
- Please could you say a bit about whether you think using them made you feel more confident about having treatment?
- Were there any other positives you experienced because of using them?
- Were there any negative things you experienced because of using them?
- Please could you tell me a bit about whether you think you will feel more confident or less worried about needles in the future because of using the resources?

Mechanisms

- What bits/pages of the resource did you think were most useful and why?
- Could you tell me a little bit about whether using the resources changed how you felt before, during or after the visit? (feelings/symptoms)



- Could you tell me a little bit about whether using the resources made you think any differently about needles? (thoughts)
- Could you tell me about whether using them changed how comfortable or worried you were about needles?
- Did they make any difference to how much you felt able to trust the person (be specific related to their treatment – nurse, dentist, doctor)? (feelings)
- Could you tell me about whether using the resources changed how you were able to talk to the person (as above) or let them know how you were feeling? (behaviours/situation)

Experience of participating

- How did you find taking part in the study?
- What did you think about the information you were given ?
- Did other people know you took part?
 - How, told or noticed
- Would you do something like this in the future?
 - Why/why not
- If there was a chance you would not have been able to use the resource, but would still have done the paperwork, would you still take part?
- Is there anything that would make it more likely that you would take part in a study like this in the future?
- Is there anything that would put you off taking part in a study like this in the future?

Experience of questionnaires and outcome measures

- How did you find the paperwork/questions we gave you to fill out? (Prompt around time taken, content, ease of understanding and format)
- Which of the questions about your needle fear did you think was best? Can you tell me why?
- What did you think of the timing of answering the questions? (Prompt to expand if suggesting timing was poor/not ideal)

Closing

- Is there anything we haven't talked about today which you would like to mention?
- Are there any ways the resources could be improved?
- What could we do to make having a needle easier for you or other young people?

Next steps

- Thank them for taking part
- Check if they have any questions about the research
- Repeat about confidentiality and anonymity
- Remind them that the findings will be published and used to create a resource for children and young people
- The findings will be shared on the website in lay language, and we can send them a copy if they would like (confirm how to send)
- Give them their thank you voucher

Appendix 24 - Topic Guide for Stage Two Qualitative Interviews Parent/Carer



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No Need(le) To Worry: Development and feasibility study of a self-help cognitive behavioural therapy resource for childhood needle fear

Topic Guide – Parent/Carer Stage 2 interviews

Introduction

Purpose is to talk to parents and carers about their experiences, and their child's experiences, of using the self-help resources

Key information

- Interview will last as long as they like but usually around 45 minutes
- Interview will be recorded on a digital recorder
- Not a test, no right or wrong answers
- Don't have to discuss anything they don't want to
- Can change their mind at any time, or ask for a break
- Information provided will be anonymised
- Can choose a different name for the tape

Background

- In the past, what has been your experience of taking (child) for appointments where they've needed an injection or needle?
- How do you feel about needles yourself?
- What treatment did your child have after using the resource?

Acceptability

Child resource

- How do you think (your child) found using the resources – the guide, message to dentist and activities?
- What are your thoughts on these resources?
- What was your role in supporting your child in using the resource?

Parent/Carer Stage 2 Qualitative Interviews Topic Guide V1.0 (03.08.2022)

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Parent resource

- Did you manage to look at the parent resources?
- If yes - What did you think about the parent resources?
 - Were there any bits or suggestions which you found most useful?
 - Were there any bits or suggestions which you thought were less useful?
 - What did you like about using them?
 - What did you not like about using them?
- Please could you say a little about whether you would encourage (child) to use the resources again in the future?
- Please say a little about whether you think you might use the parent resource again in future?

Perceived effectiveness

- Do you feel using the resources helped your child feel less worried or anxious about needles?
 - If yes - in what ways do you think it made them feel less anxious/worried?
 - If no – why don't you feel it helped them?
- Please could you say a bit about whether you think using the resources changed your experience of supporting (child) to attend the appointments/have their vaccination?
- Please could you tell me a bit about whether you think you will feel more confident supporting (child) to have a needle in the future?
- Please could you say a bit about whether you think using the resources influenced (child's) ability to receive their treatment?
- Please could you tell me a bit about whether you think you will feel more confident supporting (child) with receiving treatment in the future?
- Were there any other benefits that (child) experienced because of using the resources?
- Were there any negative things you think (child) experienced because of using the resources?
- Please could you say a bit about whether using the resources has influenced your own feelings about needles?

Mechanisms

- What bits/pages of the parent resource did you think were most useful and why?
- What bits/activities of the child resource did you think were most useful and why?
- In your opinion, how did the booklet/resource influence the way in which your child views needles? (thoughts)
- In your opinion, how did the booklet/resource influence your child's ability to trust the (insert correct from nurse dentist doctor)? (feelings)



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- In your opinion, how did the booklet/resource influence yours or your child's ability to be able to talk to the (nurse, dentist, doctor) or let them know how you/they were feeling? (behaviours/situation)

Experience of participating

- How did you feel about your child taking part in this study?
- Can you tell me your views on the information you received about the study?
- Would you do something like this in the future?
 - Why/why not
- If there was a chance your child would not have been able to use the resource, but would still have done the paperwork, would you still take part?
- Is there anything that would make it more likely that you would take part in a study like this in the future?
- Is there anything that would put you off taking part in a study like this in the future?

Closing

- Covered everything, or is there anything else you want to discuss?
- Are there any ways either the child or parent resources could be improved?
- What could healthcare workers do to make treatment with needles easier for young people?
- What could healthcare workers do to better support parents of young people with needle fear?

Next steps

Thank them for taking part
Check if they have any questions about the research
Repeat about confidentiality and anonymity
Remind them that the findings will be published and used to create a resource for children and young people
The findings will be shared on the website in lay language, and we can send them a copy if they would like (confirm how to send)
Give them their thank you voucher

Appendix 25 - Topic Guide for Stage Two Qualitative Interviews Healthcare Professionals – Treaters



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No Needle To Worry: Development and feasibility study of a self-help cognitive behavioural therapy resource for childhood needle fear

Topic Guide – Healthcare Professionals Stage 2 Interviews (Treatment)

Introduction

- Introduction to the study – looking at their experiences of using the resources –
- Establishment of ground rules
- No right or wrong answers, healthcare worker is the expert
- Use of a tape recorder by the researcher to avoid having to take notes
- Confidentiality-responses will not be shared with children, parents, other dental professionals or service commissioners etc.
- Participants to choose a different name they would like to be referred to on the tape
- Can terminate the interview at any time if required

Background to treating young people who have needle fear

- Opening question: How do you feel about treating children with needle fear?
- How have you managed needle fear in the past?

Response

- Please could you tell me a bit about your experience of using the child self-help resource with your patients?
- Please explain whether using the resources changed how you feel about treating children with needle fear?
- What are your thoughts on how the parent resources worked? (if relevant)
- What are your thoughts about how the resources overall helped you manage children's needle fear? More specifically, how did it help you provide and/or complete the treatment for the young person?
- What are your thoughts about how the resources helped young people (and their carers) manage needle fear themselves now and potentially in future?
- What aspects of the resources do you think were most useful/effective?
 - Specific aspects of parent/child/HCW resource?
 - Why do you think this might be?

Healthcare Professionals Stage 2 Qualitative Interviews (Treatment) Topic Guide V1.0 (03.08.2022)
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- Were there any young people (or groups of young people) that it seemed to work better or worse for?
 - Why do you think this might be?
- Were there any other benefits you noticed as a result of using the resources?
- Any negative outcomes you noticed as a result?
- Would they suggest to a colleague that they should recommend the resource for any anxious patients that they may see?

Context

- Were there any external factors that you feel would help/support you in being able to implement the intervention? (environmental context/resources)
- What there any external factors that you feel would make implementing the intervention more challenging? (environmental context/resources) Might cost or time be an issue?

Closing

- Have we covered everything, or is there anything else you want to raise?

Next steps

Thank them for taking part
Check if they have any questions about the research
Repeat about confidentiality and anonymity
Remind them that the findings will be published and used to create a resource for children and young people
The findings will be shared on the website in lay language, and we can send them a copy if they would like (confirm how to send)
Give them their thank you voucher

Appendix 26 - Topic Guide for Stage Two Qualitative Interviews Healthcare Professionals – Recruiters



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No Need(le) To Worry: Development and feasibility study of a self-help cognitive behavioural therapy resource for childhood needle fear

Topic Guide – Healthcare Professionals Stage 2 Interviews (Recruiters)

Introduction

- Introduction to the study – looking at their experiences of recruitment –
- Establishment of ground rules
- No right or wrong answers, healthcare worker is the expert
- Use of a tape recorder by the researcher to avoid having to take notes
- Confidentiality-responses will not be shared with children, parents, other dental professionals or service commissioners etc.
- Participants to choose a different name they would like to be referred to on the tape
- Can terminate the interview at any time if required

Background to treating young people who have needle fear

- Opening question: How do you feel about treating children with needle fear?
- How have you managed needle fear in the past?

Recruitment

- Please could you tell me a bit about your experience of recruiting patients to the study?
- Did you feel well prepared to recruit?
- Did you feel supported to recruit?
- Were there any obvious barriers to you recruiting patients?
- Did you notice any barriers to patients taking part?
- Is there anything that you found helpful when recruiting patients?
- Is there anything that you found very difficult about recruiting patients?
- Were you able to recruit the targeted number of participants?



Future study

- In your opinion, if a larger scale study were to run (which would need lot more patients), would it be a good idea to recruit in your setting?
 - Why/Why not?
- In your opinion, if a larger scale study were to run (which would need lot more patients), would it be a good idea to recruit in your setting?
 - Why/Why not?
- Would you suggest any other settings for recruitment?
 - Explain why?
- If patients were to be randomized in the larger study, i.e. some would not receive access to the resource, how would you feel about recruiting?

Closing

- Have we covered everything, or is there anything else you want to raise?

Next steps

Thank them for taking part
Check if they have any questions about the research
Repeat about confidentiality and anonymity
Remind them that the findings will be published and used to create a resource for children and young people
The findings will be shared on the website in lay language, and we can send them a copy if they would like (confirm how to send)
Give them their thank you voucher