“Exploring the value of dietary intervention in the management of psychosis: a mixed method study”

Kevin Wayne Williamson

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Abstract

Psychosis is a clinical syndrome that has a large impact on individuals and their families. Current treatment is not fully efficacious. The formation and function of the brain is dependent upon nutrients, supplied through the diet. Despite this, evidence indicates that diets, particularly for those with psychosis are sub-optimal in terms of nutritional value. The aim of this PhD therefore was to explore the value of diet intervention for psychosis management, which was rooted in Pragmatism and followed an explanatory sequential mixed-methods design aligned to the Medical Research Council's (MRC) Framework for the development and evaluation of complex healthcare interventions (Skivington et al., 2021).

The first part of this PhD was the conduct of a systematic review and meta-analyses, the outcome of which was that no suitable diet intervention existed for psychosis management. The findings informed interview topic guides for two qualitative studies that sought the views of: (i) healthcare professionals (HCPs) experienced in psychosis management and (ii) patients and carers on diet intervention for psychosis management. The data was thematically analysed separately (Braun and Clarke, 2006) into four themes for each respective study. Findings from these studies were synthesised into a Pipeline Logic Model, following the principles of triangulation (Farmer et al., 2006). This provided the contextual factors and elements of programme theory required to develop and deliver a diet intervention for psychosis management. Stakeholders would value diet intervention for psychosis management, delivered by trained HCPs within NHS mental health services. The evidence-based diet intervention should be accessible to patients and should lead to the necessary dietary knowledge and skills. The principal recommendation following this PhD is to further develop a diet intervention for psychosis management with an increased stakeholder group, which should include NHS mental health service commissioners and academics responsible for HCP pre- and post-registration curricula.

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List of Abbreviations

AA	Arachidonic Acid
ATP	Adenosine TriPhosphate
AMED	Allied and Complementary Medicine Database
ANCOVA	ANalysis of COVAriance
ANOVA	ANalysis of VAriance
BDA	British Dietetic Association
BNI	British Nursing Index
BPRS	Brief Psychiatric Rating Scale
CAARMS	Comprehensive Assessment of At Risk Mental State
CBT	Cognitive Behavioural Therapy
CGI	Clinical Global Impressions
CGI-SCh	Clinical Global Impressions- Schizophrenia
CI	Confidence Interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CMHT	Community Mental Health Team
CPD	Continuous Professional Development
CONSORT	Consolidated Standards for Reporting Trials
CQC	Care Quality Commission
CQUIN	Care QUality INdicator
DoH	Department of Health
DHA	Docosahexaenoic Acid
EIP	Early Intervention in Psychosis
EPA	Eicosapentaenoic Acid
GEE	Generalised Estimated Equations
HCP	Healthcare Professional
HCPC	Healthcare Professions Council
HBE	Health Business Elite
HDAS	Healthcare Databases Advanced Search
HMIC	Healthcare Management Information Consortium
HRA	Health Research Authority
ICD	International Classification of Diseases
IRAS	Integrated Research Application System
IU	International Units
L-DOPA	L-3,4-dihydroxyphenylalanine
MCID	Minimum Clinically Important Difference

MDT	Multi-Disciplinary Team
MeSH	Medical Subject Headings
MMRM	Mixed Model for Repeated Measures
MRC	Medical Research Council
NHS	National Health Service
NHSE	National Health Service England
NICE	National Institute for health and Care Excellence
NMC	Nursing and Midwifery Council
NR	Not Reported
NREC	National Research Ethics Committee
OASIS	Overall Anxiety Severity and Impairment Scale
PANSS	Positive and Negative Syndrome Score
PhD	Doctor of Philosophy
PICU	Psychiatric Intensive Care Unit
PIS	Participant Information Sheet
PPIE	Patient and Public Involvement and Engagement
PRA	Patient Research Ambassador
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO	International Prospective Register of Systematic Review Protocols
PSI	Psychosocial Intervention
PUFA	Polyunsaturated Fatty Acids
QIDS	Quick Inventory of Depressive Symptoms
RCT	Randomised Controlled Trial
RMO	Responsible Medical Officer
SEM	Standard Error of Mean
SFA	Saturated Fatty Acids
SMI	Severe Mental Illness
TTM	Transtheoretical Model
WHO	World Health Organization

1. INTRODUCTION

The PhD has been founded in philosophical Pragmatism with the use of an explanatory sequential mixed methods (Creswell and Plano-Clark, 2017) design to examine the phenomenon in question. This thesis documents the elements comprising this PhD, which explored the value of diet intervention for the management of psychosis, using mixed methods. Firstly, a quantitative (explanatory) method was used in the systematic review of the literature, including two meta-analyses of included studies. As the review found no diet interventions effective at psychosis management, the next elements of the PhD, informed by the review findings, were two concurrent qualitative studies. These studies sought the views of key stakeholders: Healthcare Professionals (HCPs) (study 1) via a series of focus group interviews and Patients and Carers (study 2) via a series of individual semi-structured interviews. Thematic analysis (Braun and Clarke, 2006) was conducted on the datasets within each of these studies and themes were constructed and discussed. The results of these individual studies explored the context of the phenomenon being investigated: the value of diet intervention for psychosis management, from the perspectives of the respective stakeholder groups. The final element of this PhD was to synthesise the two qualitative studies' findings to elucidate the core elements of a diet intervention for psychosis management. These elements, represented in a pipeline logic model (Funnell and Rogers, 2011) include the key inputs, activities, outcomes and impact and any assumptions and external factors of relevance. Alongside the core elements of the diet intervention are the areas of silence in the data and the implications and suggested next steps following completion of this PhD.

The thesis begins with this introductory chapter, which outlines the research question and aim at the centre of this PhD, followed by a note on the use of reflective excerpts within this thesis as a means of adding value, proceeding with a summary overview of each of the thesis' chapters. The paragraphs/sub-sections within this introductory chapter (Chapter 1) mirror the chapters in the thesis. Following this first chapter, is a chapter (Chapter 2) detailing the background and rationale for this PhD. The methodological foundation for this PhD (Chapter 3) succeeds this, followed by the systematic review of the literature and subsequent meta-analyses conducted to determine the efficacy of any diet interventions at psychosis symptom management (Chapter 4). The practical methods used in the conduct of the two qualitative studies is then provided (Chapter 5). There are two chapters reporting and discussing the individual findings of two concurrently conducted qualitative empirical studies, which sought the views of stakeholders: HCPs (Chapter 6) and Patients and Carers (Chapter 7) in the development of a diet-related intervention for psychosis management.

Chapter 8 reports and discusses synthesised findings across both studies, which elucidated the core elements of a diet intervention, articulated in a logic model. The final chapter(s) of this thesis (Chapter 9) details the implications of the findings of this PhD and the subsequent recommendations for the development of a diet intervention following completion of this PhD. These are followed by the limitations associated with the conduct of this PhD.

1.1 PhD question and aim

The following question was developed and refined throughout the early phases of the conduct of this PhD inquiry:

> *"Is there value in providing a diet intervention for the management of psychosis?'*

The aim of conducting this PhD is to explore the value of providing effective diet intervention as part of the management of psychosis. The term 'value' here articulates a pragmatic approach to determining the merit of providing a diet intervention for psychosis management. The methods used, and findings produced, are detailed in the chapters of this PhD thesis.

1.2 Researcher Positionality

The researcher chose the PhD topic as a professional who had worked as a nutritionist within psychosis services. Following a change of career from clinical practice into research, the researcher was aware that this was still an under-researched area and wanted to take the opportunity of PhD study to further the knowledge base on this. The PhD's theoretical underpinnings have directed the conduct of the PhD, but the researcher acknowledges that this mixed methods approach is something that they align with.

1.3 Use of reflective excerpts within the thesis

In addition to the clearly defined chapters to summarise the key messages related to this PhD, there are also included excerpts from the Researcher's own research diary. These have been included from a Pragmatist point-of-view where it was thought that their inclusion would add value to the written text. The value they add is at increasing the transparency of the conduct of this PhD (Davis, 2020). Examples of this 'value' include highlighting certain thought processes that contributed to a given decision, alongside examples of challenges encountered during the conduct of this PhD. These excerpts are demarcated in a separate text box at various points throughout the thesis.

1.4 Definition of the terms ‘dietary intervention’ and ‘nutritional intervention’

Throughout the conduct of this PhD, a dietary intervention refers to an intervention for the purposes of health concerning anything that relates to a person’s diet, including the habits by which they consume foods. Likewise, throughout the PhD, a nutritional intervention refers to an intervention for the purposes of health improvement and relates to the oral consumption of food or their component parts which the body will absorb.

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2. BACKGROUND

This chapter summarises peer-reviewed literature and guidance that provide the context and rationale for undertaking this PhD. This PhD is guided by the concept that a psychotic symptom is a manifestation of sub-optimal, or altered, brain function. All symptoms of psychosis, irrespective of their causal factors and irrespective of existing models of treatment, manifest as the result of physiological or biochemical processes in the brain. Furthermore, this PhD is built upon the certainty that like all other organs within the body, brain function is directly dependent upon nutrients sourced from the diet. The rationale for exploring diet as part of psychosis management is therefore made throughout this chapter. Key processes within the functioning brain are known to be altered with psychosis, including the biochemical process called neurotransmission, which is the communication mechanism within the brain and between the brain and other parts of the body is known to be altered during psychosis. Neurotransmission, which is currently a key treatment option for psychosis, is known to be affected by nutrients. This background chapter proceeds with sections considering how diet could complement current treatment strategies, the current dietary habits of those with psychosis and concludes with a section detailing policy guiding dietary intervention for the management of mental health problems, such as psychosis.

2.1 Overview of Psychosis

Psychosis is a clinical syndrome, comprising symptoms, such as delusions, hallucinations and thought disorder as core examples (Gaebel and Zielasek, 2015), whereby the individual displays a lack of insight (Arciniegas, 2015). The American Psychiatric Association historically described psychosis as a major loss of the individual’s ability to discern and test reality (APA, DSM-II, 1968). The term psychosis has evolved to include advances in scientific understanding of the causes and processes governing psychosis (Beer, 1996; Bürgy, 2008; Gaebel and Zielasek, 2015). The International Classification of Diseases, 11th edition (ICD-11), lists coded diagnostic criteria allowing accurate classification of all known diseases and health conditions (World Health Organization, 2023). During the process of clinical assessment, the symptoms of psychosis are usually classified into: “positive”, “negative” and “general” symptom domains as directed by validated instruments (Kay et al., 1987; Arciniegas et al., 2015).

2.2 Physiological and Biochemical processes inherent to the manifestation of psychosis symptoms

Psychosis symptoms, irrespective of type, manifest through sub-optimal brain function, particularly of the neurotransmitter dopamine (Richtand and McNamara, 2008; Brisch et al., 2014). The neurotransmitter dopamine is used within several of the body’s key systems and helps control feelings of mood, pleasure and motivation (Wise, 2004), as well as blood pressure and kidney function (Harris and Zhang, 2012). It has long been postulated that the positive symptoms of psychosis occur as a result of increased neurotransmission involving dopamine (Brisch et al., 2014), whereas negative symptoms are as a result of decreased dopaminergic neurotransmission (Correll and Schooler, 2020); this has been termed the 'Dopamine Hypothesis' (Carlsson and Lindqvist, 1963) (see Section 2.5 on pharmacological treatments). Whilst investigation has been conducted into the impact of other neurotransmitters, such as serotonin on psychosis, the evidence is limited (Lin et al., 2014) and current pharmacological treatments remain linked to dopamine pathways. A further description of psychosis symptoms and key features of the symptom domains are provided in the next sections.

2.2.1 Positive symptoms

Positive symptoms represent an excess or addition to normal function and include hallucinations, delusions and thought disorder (Correll and Schooler, 2020).

2.2.1.1 Hallucinations

Hallucinations are defined as sensory perceptions in the absence of the corresponding external stimulus/stimuli, which are characterised by the corresponding sensory domain, e.g. voices are auditory hallucinations (Arciniegas, 2015). As a clinical syndrome, psychosis symptoms are linked to thought disorder and lost perception of reality (Gaebel and Zielasek, 2015), because of this, individuals often have little insight that their experiences are in fact hallucinations and not reality, as perceived by others (Arciniegas, 2015).

2.2.1.2 Delusions

Delusions are defined as fixed beliefs that 1) are false and are based upon an incorrect inference about reality that are external to, or about oneself and 2) remain in place despite clear, unequivocal evidence to the contrary (Arciniegas, 2015). Some delusions relate to ordinary experiences and whilst false, are highly plausible, whereas others are bizarre in nature and are usually implausible and often impossible (Arciniegas, 2015).

2.2.1.3 Thought disorder, as represented by disorganised speech

Disordered thoughts and disorganised speech are phenomena characterised by a derailment of thought processes and a tendency to tangentiality, often in conjunction with overly concrete thought processes (Cicero et al., 2022). The disorganisation is also associated with a tendency toward illogical thoughts and incoherent speech (Cicero et al., 2022).

2.2.2 Negative Symptoms

Negative symptoms represent a reduction or absence of some key aspects of normal behaviour, such as behaviours that link to motivation, expression or interest (Correll and Schooler, 2020). Negative symptoms are common symptoms of psychosis, with almost 60% of patients having persistent negative symptoms that limit functioning for an individual and thus warrant treatment (Correll and Schooler, 2020). The five main domains of negative symptoms are blunted affect (diminished facial and/or emotional expression), alogia (marked reduction in spoken words), avolition (marked reduction in aspiration and goals, linked to reduced motivation), associality (lack of, or marked reduction in socialising) and anhedonia (lack, or loss of pleasure) (Kirkpatrick et al., 2006; Correll and Schooler, 2020).

Negative symptoms are less likely to be resolved from taking antipsychotic medication and tend to represent an unmet need in terms of psychosis management (Carbon and Correll, 2014). The negative symptoms of psychosis often result in the reduced global functioning of those with psychosis and are thought to contribute to some of the co-morbidities associated with psychosis (Galderisi et al., 2018). An exploration of further treatment options for negative symptoms of schizophrenia is warranted (Galderisi et al., 2018).

2.2.3 General Symptoms

There are four general symptom domains listed in the ICD-11 (WHO, 2023), which are manic mood, depressed mood, psychomotor and cognitive symptoms, all of which should be rated as part of a diagnostic assessment (WHO, 2023).

2.3 Relationship between psychosis and diagnostic criteria

As a clinical syndrome, ‘Psychosis’ is present in a variety of mood and substance use disorders, however it is commonly associated with the schizophrenia spectrum disorders (‘Schizophrenia’), as it is schizophrenia’s classic symptom and thus its defining feature (Jablensky, 2010; Arciniegas, 2015). According to the World Health Organization (WHO), schizophrenia is currently listed as a “severe mental disorder” and is characterised by disorganised thinking and a detachment from reality, diagnosed through the presence of psychotic symptoms, such as delusions, hallucinations, and hearing voices (WHO, 2022). Perala et al. (2007) investigated the lifetime prevalence of psychotic disorders and reported that only 30% of those with a psychotic disorder would be classified as having schizophrenia. Guloksuz and van Os (2018) discussed this finding in the context of the need to consider psychosis as being on a continuum and that consideration of a psychosis spectrum disorder could facilitate more accurate treatment.

2.4 Current Treatment strategies for Psychosis

This section describes the current treatments used to manage psychosis. These strategies are explained, including a description of key features and issues associated with treatment, including side effects associated with medication. The issues noted with current treatment strategies indicates scope for additional treatment options to be explored, such as this PhD, which seeks to explore the value of diet for psychosis management. It is important to note though that exploring the value of diet in the management of psychosis should not detract from the existing value of recommended treatment approaches. Instead, it seeks to consider an additional approach, the use of diet, in terms of its efficacy at managing psychosis.

Current treatment strategies in the United Kingdom are centred around pharmacological and psychological interventions, as directed by the National Institute for Health and Care Excellence's (NICE) guideline entitled 'Psychosis and Schizophrenia in adults: prevention and management (Nice Guideline CG178) (NICE, 2022). In England, 82.4% of all individuals diagnosed with psychosis received treatment using one or both of those strategies (McManus et al., 2016). Almost all of those in receipt of treatment for psychosis in England (in 2014) were actively prescribed psychotropic medication and just over half (54.4%) had received psychological intervention within the last year (McManus et al., 2016). Treatment strategies for psychosis may vary across the course of psychosis treatment, with psychotropic medication supporting acute symptoms whereas psychological interventions are framed around psychological education which empowers individuals and members of their care network to understand the illness and identify potential triggers, thus encouraging them to engage with their treatment plans (Frank and Gunderson, 1990).

The recommended approaches to the treatment of psychosis also consider the broader health needs of individuals and their families and that early treatment, or better still, prevention is warranted (NICE, 2022). To that end, investment has been made to fund clinical teams specialising in the care of those with first episode psychosis where the aims are to prevent the onset of schizophrenia and to improve the prognosis for those that have experienced psychotic symptoms (Marshall and Rathbone, 2011). The following sub-sections describe firstly the pharmacological treatments and then the psychological treatments used to manage psychosis, including issues relating to side effects and low compliance.

2.5 Pharmacological treatment for psychosis

2.5.1 Discovery and Chronology of usage

The dopamine hypothesis for psychotic symptoms was developed following the accidental discovery of antipsychotic drugs in the 1950s when Hamon and colleagues and Delay and colleagues administered chlorpromazine for anaesthesia during surgery to psychiatric patients (Shen, 1999). This was followed by subsequent testing in murine models in the 1960s by Carlsson and Lindqvist, which revealed that these drugs increased dopamine metabolism (Carlsson and Lindqvist, 1963) (See Table 2.1). Shen (1999) reported that between 1954 and 1975 there were 40 antipsychotic agents introduced worldwide - known laterally as the ‘typical’ or ‘first generation’ antipsychotics. There was a hiatus of new antipsychotic agents until the advent of clozapine in the 1970s, which was the first ‘atypical’ or ‘second generation’ antipsychotic agent. Clozapine provided symptom improvement for those that had previously been determined as treatment-resistant (Shen, 1999).

Table 2.1: Chronology of the discovery and development of antipsychotic medication (Adapted from Ramachandraiah et al., 2009)

Timeline (Decade)	Development or discovery	Function in psychosis symptom management
1940s	Promethazine, a phenothiazine derivative, along with barbiturates used for anaesthesia.	This agent was noted for its anxiolytic properties and its ability to calm the effects of agitation.
1950s	Chlorpromazine was developed and tested by psychiatrists tentatively. In 1955 a case series of the effects on 38 patients was presented.	Noted for calming properties of acute symptoms, with an effect which could be maintained Extra-pyramidal side effects noted.
	Haloperidol was developed in Belgium in 1958 in pursuit of analgaesic agents.	Sedative and hallucinolytic properties Extra-pyramidal side effects noted.
1960s	Clozapine was tested in humans and was considered to be	Effective hallucinolytic No extra-pyramidal side effects side effects noted, and was

Timeline (Decade)	Development or discovery	Function in psychosis symptom management
	effective, but with no neuroleptic side effects.	labelled ‘atypical’ as an antipsychotic.
1970s	Clozapine launched onto the market.	Efficacy noted, however side effect of agranulocytosis and sudden death observed in patients.
1990s	Advent of several other antipsychotics: risperidone, olanzapine, quetiapine, ziprasidone.	which were similar to clozapine in that they were efficacious but without extra-pyramidal side effects and were thus ‘atypical’.
2000s	Observation that the ‘atypical’ antipsychotics were associated with metabolic disorder, weight gain and markers for diabetes.	

A refinement of this model the ‘modified dopamine hypothesis of schizophrenia’ was developed and published in 1991 (Davis et al., 1991). The 1991 hypothesis was based on evidence of abnormal, not excessive, dopamine activity in key brain regions of those with schizophrenia (Davis et al., 1991), which then formed the basis of pharmacological treatment for psychotic symptoms until a third version of the dopamine hypothesis, entitled ‘The Dopamine Hypothesis of Schizophrenia: Version III – The Final Common Pathway’ (Howes and Kapur, 2009) incorporated the effect of environmental and genetic risk factors that interact through one common pathway of presynaptic striatal hyperdopaminergia, thus influencing psychotic symptoms (Howes and Kapur, 2009). This revised hypothesis indicated that the pathways that influence psychosis are potentially more complex than originally thought (Howes and Kapur, 2009). A recent narrative review of the evidence suggests that the dopamine dysregulation responsible for manifesting psychosis is potentially influenced by factors such as stress or trauma, which may have adversely altered brain development at critical timepoints, such as puberty (Sonnenschein et al., 2020). This indicates that as stress and other factors are likely to influence the manifestation of psychosis, there is a need to consider exploring new or alternative treatments for psychosis management. This supports the conduct of this PhD which seeks to explore the value of diet for psychosis management.

2.5.2 Mechanisms of action

Miyamoto and colleagues (2005) reviewed the therapeutic agents for schizophrenia and found three basic classes of medication: conventional (typical), atypical and dopamine partial agonist antipsychotics, all of which work through the dopaminergic pathways. The D(2) dopamine receptor is the target for antipsychotic agents and the action of antipsychotics is to improve neurotransmission and abate the symptoms of psychosis (Miyamoto et al., 2012). These are the only proven pharmacological therapeutic mechanism for psychoses (Miyamoto et al., 2012). Seeman (2002) stated that the atypical antipsychotics, aid symptoms by transiently occupying D2 receptors and then rapidly dissociating to allow normal dopamine neurotransmission.

2.6 Implications and issues with psychotropic treatment/medication

The development of both the first and second-generation antipsychotics provided a feasible treatment option for psychosis symptoms, however these agents were not perfect. It transpired that some individuals' psychosis did not respond fully to the treatments and there were side effects associated with both the first generation and second-generation antipsychotics (Ramachandraiah et al., 2009). Some of the early antipsychotic agents led to sudden deaths, through increased risk of arrhythmias (Ray et al., 2009), which increased the desire to develop newer treatments, leading to the second-generation, 'atypical' antipsychotics, such as olanzapine and clozapine, As outlined in Table 2.1.

2.6.1 Metabolic disturbance

This section describes the metabolic disturbance associated with pharmacological treatments, which indicates firstly that current treatment isn't an ideal solution, thus warranting alternative interventional strategies as part of psychosis management and secondly, that there is a logical link between metabolism and diet. Several years after the introduction of the 'atypical' antipsychotics such as olanzapine, risperidone and clozapine it was noted that people treated with them had gained weight and had a tendency to develop diabetes (Newcomer, 2005). This was initially disregarded as a consequence of the pharmacological agent, but viewed as a consequence of hyperphagia and an altered lifestyle of individuals (Stefanidis et al., 2009). Hyperphagia has been explored further and a suggestion that cravings exist for processed or 'fast-foods' in those who are overweight or obese compared to those with a healthy weight at the start of taking clozapine (Garriga et al., 2019). Allison et al. (2003) surveyed 286 individuals with schizophrenia regarding weight gain in the first 6 months of taking atypical antipsychotic medication and reported that of the 44% who gained weight, 19% gained 0-10 pounds, 12% gained 11-20 pounds and 14% gained more than 20 pounds. The limitation that self-reported weight gain data may be underestimated must be acknowledged. Antipsychotic agents exerted undesirable physiological effects on some patients such as dyslipidaemia and hyperglycaemia and an increased risk of diabetes (Newcomer, 2005). For two agents – clozapine and olanzapine – their action on metabolic indices was independent of adiposity (Newcomer, 2005). Jeon and Kim (2017) reported that atypical antipsychotics continued to contribute to metabolic problems, abnormal lipid and glucose metabolism and the consequent physical manifestations of those problems, including obesity, diabetes and cardiovascular disease.

2.6.2 Lipid Profile changes

A prospective longitudinal study following a cohort of medication-naïve first episode patients was conducted to assess changes in weight and the incidence of metabolic abnormalities (Pérez-Iglesias et al., 2014). Data was collected and analysed from a cohort of 170 drug-naïve first episode psychosis patients who were assigned, as part of their usual care, to three different antipsychotic agents: risperidone (36%), haloperidol (32%) and olanzapine (32%) (Pérez -Iglesias et al., 2014). The results indicated a significant mean weight gain at 3 years post-baseline of 12.7kg (SD=12.7; $p<0.001$) (Pérez -Iglesias et al., 2014). Weight gain increased rapidly at the outset for all three agents, with olanzapine posing the highest risk for weight gain within the first three months and a total weight gain of 85% arose within the first-year post-baseline (Pérez - Iglesias et al., 2014).

Feng and Melkersson (2012) reported that hyperlipidaemia is associated with two different antipsychotic agents – clozapine and olanzapine; they suggest these agents may have a causal relationship. A similar study in Iceland also reported a significantly increased risk (2.3 times in males (95% CI: 1.4-3.5; $P<0.001$) and 4.4 times in females (95% CI: 2.1-7.8; $p<0.001$) of developing type two diabetes in those with schizophrenia prescribed antipsychotic medication (clozapine; n=188) compared to population controls (n=355) (Ingimarsson et al., 2017). A recent meta-analysis with 59 included studies, determining the effect of switching antipsychotic medication found that Aripiprazole significantly reduced weight (−5.52 kg, 95% CI −10.63, −0.42, p=0.03) and triglycerides (−31.03 mg/dl, 95% CI −48.73, −13.34, P = .0001), whilst olanzapine significantly increased weight (2.46 kg; 95% CI: 0.34, 4.57, p=0.02) (Siskind et al., 2021).

2.6.3 Hyperglycaemia and changes in glucose metabolism

In addition to changes in the lipid metabolism of those with psychosis, there are also changes to their glucose profile evident in an increased risk of developing type-2 diabetes mellitus (Pillinger et al., 2017). Antipsychotic medication may increase the morbidity burden of type two diabetes mellitus in those with psychosis due to hyperphagia (Stefanidis et al., 2009) and food craving (Garriga et al., 2019) in individuals. A finding from the systematic review and meta-analysis of 59 studies noted in the previous section also indicates switching to aripiprazole can significantly reduce fasting glucose levels (−3.99 mg/dl, 95% CI: −7.34, −0.64, p=0.02).

There seems to be clear evidence of altered lipid and glucose metabolism in those with psychosis prior to the initiation of anti-psychotic medication (Pérez -Iglesias et al., 2014), which remains or is worsened by some antipsychotic agents (Feng and Melkersson, 2012). Irrespective of the underlying mechanisms and causal factors, these changes are likely to have a large impact on the physical health of those with psychosis. Evidence has shown a decrease in the health-related quality of life for obese individuals with schizophrenia versus those who were within normal weight range (Kolotkin et al., 2008).

2.6.4 Metabolism-associated mortality in those with psychosis

There has long been debate as to whether these associated co-morbidities were physiologically driven, or whether they were environmentally driven, through the lifestyle choices of patients. De Hert and colleagues (2009) reviewed these factors and concluded that they represented an increased risk of premature mortality to patients. Evidence from a Finnish cohort reported that at 17-years follow up, the relative mortality risk between those with schizophrenia (n=99) and population controls (n=7118) was 2.25 (95% CI 1.61-3.15) after adjustment for somatic diseases, metabolic indices, smoking, exercise, education and alcohol intake (Joukamaa et al., 2006). This finding prompted the recommendation that research was urgently required to ascertain whether high mortality in those with schizophrenia was attributable to the condition or to the treatment used (antipsychotic medication) (Joukamaa et al., 2006). A systematic review published in 2009 examined 12 primary research studies and concluded that there was evidence that long-term exposure to antipsychotic medication increased mortality in schizophrenia and that this warranted more rigorously designed, prospective studies to be conducted (Weinmann et al., 2009). Animal models have also demonstrated that abdominal fat deposition can occur whilst undergoing treatment with antipsychotic medication, irrespective of a corresponding change in energy intake (Cooper et al., 2007). This effect, found to be reversible following the cessation of the pharmacological agent (Cooper et al., 2007), emphasises the need for robust nutritional assessment and intervention for those receiving treatment with antipsychotic medication. These findings suggest that cell signalling pathways are altered in the presence of antipsychotic agents (Cooper et al., 2007).

Tiihonen and colleagues (2009) examined Nationwide Health registers from Finland between 1996 and 2006 to determine whether there was any variance in the all-cause mortality of patients diagnosed with schizophrenia between that time period. They reported that the gap in life expectancy did not vary greatly between 1996, where it was 25 years lower than the general population, and 2006 where it was 22.5 years lower than the population mean (Tiihonen et al., 2009). They considered this finding in the context of a proportional increase in second-generation antipsychotic drug usage (from 13% to 64%) and that antipsychotic medication was linked to a lower mortality gap compared to taking no medication (Tiihonen et al., 2009). The interpretation of these findings was the subject of debate (Basu and Aggarwal, 2009; Chwastiak and Tek., 2009; De Hert et al., 2009; Dervaux and Laqueille, 2009; Sperling and Biermann, 2009). Basu and Aggarwal (2009) considered that these findings were set in the context of individuals accessing more appropriate treatment for the management of their psychotic symptoms and could therefore be a proxy for accessing and engaging with long-term healthcare use. Chwastiak and Tek (2009) considered it noteworthy that this excessive gap remains despite a national health system where the standard of care should be equal for all residents, which links to the associated burden of psychosis, as described further in Section 2.9. Current best practice for the management of antipsychotic medication administration at the outset of a psychotic episode in the United Kingdom reflects the impact of side effects and thus advocates that the choice of medication should be made jointly between the healthcare professional and the patient (NICE, 2022).

2.7 Psychosocial treatment strategies for psychosis

The earlier part of this chapter described the development, application and side effects associated with the pharmacological treatment of psychosis. Alongside the development of pharmacological treatments, there has been a corresponding development of psychosocial approaches to psychosis management. Psychotherapeutic intervention, also known as ‘talking therapies’ is a term comprising a range of strategies that aim to modify the behaviour, feelings or emotions of an individual (Fenn and Byrne, 2013). Psychological interventions have been found to help individuals manage their own psychosis symptoms, especially the negative symptoms of psychosis, such as apathy or lack of interest or pleasure in daily life (Gondek et al., 2017) and are recommended by NICE as part of psychosis management (NICE, 2022).

Social functioning is altered in those with psychosis and as an important consideration as part of the treatment for those affected a combination of psychological and social treatment approaches, called 'psychosocial' interventions (PSI) was developed in the 20th century, but was not always favoured by clinicians (Bellack and Mueser, 1993). Bellack and Mueser (1993) reported that a combination of biological treatments (pharmacological) and psychosocial treatments (therapy and social and occupational integration) should be considered of psychosis management. There was a view in the treatment of psychosis that pharmacological treatment was superior to psychological treatments, although by the end of the 20th century the view was changing to acknowledge the value of talking therapies (Kuipers et al., 2006). There were other factors which supported the rationale for psychological and social approaches, which included patients choosing not to take prescribed antipsychotic medication (Kemp et al., 1996) and that a proportion of individuals' symptoms persisted despite pharmacological treatment (Kane, 1996). Psychological therapy as part of the treatment of mental health issues has in recent decades been regarded positively by healthcare professionals (Prytys et al., 2011) and by patients (Jorm, 2000).

There are a range of evidence-based PSI available, such as social skills training and Cognitive Behavioural Therapy (CBT), and whilst these have merit in supporting individuals, no single method is clearly efficacious over others so a combination and tailored approach may be warranted (Kern et al., 2009). A cluster-RCT was conducted to assess the feasibility of integrated multi-element PSI with treatment as usual (n=626; 364 treatment: 262 control drawn from 117 treatment practices in a catchment area of 10 million inhabitants) (Ruggeri et al., 2015). The results of this trial included greater reduction in symptom severity following treatment compared with the control group, whilst maintaining a similar rate of retention in the treatment group (87.9%) compared to the control group (89%) (Ruggeri et al., 2015). Following a review of the literature, Breitborde et al. (2017) considered that further research should explore the pairing of appropriate PSI with technological delivery methods as a tailored approach to individuals' care.

Cognitive Behavioural Therapy (CBT) is one of the psychological therapeutic approaches recommended by NICE in the treatment of psychosis (NICE, 2022), following the success of an RCT, conducted with individuals regarded as medication-resistant (n=60) and who exhibited at least one positive symptom of psychosis at the point of enrolment (Kuipers et al., 1997). The results of this trial were a 25% reduction in overall symptomatology in the treatment group (n=28) compared to the control group (n=32) (Kuipers et al., 1997). Furthermore, 50% of the treatment group responded to the treatment regime compared to 31% in the control group indicating that almost one fifth of individuals derived benefit from psychological intervention in combination with medication and other existing treatments compared to those on standard treatment alone (Kuipers et al., 1997). This indicates that a combination of existing pharmacological treatment and psychological treatment has merit in psychosis management, which is a supported approach advocated within current best practice (NICE, 2022).

2.8 Overall efficacy of current treatment approaches

As a currently indicated first line treatment for psychosis (NICE, 2022), adherence to pharmacological treatment is likely to improve symptoms for many affected by psychosis. There is, however, evidence of non-compliance with medication, with rates of non-compliance being cited at an initial rate of 41% following systematic review of 39 published studies (Lacro et al., 2002), which when corrected through exclusion of studies with insufficient methodological rigour was 50% (Haddad et al., 2014). A more recent systematic review of the literature cited antipsychotic non-adherence for those with schizophrenia even higher at 56% (Howes et al., 2021). The causes of non-compliance include impact of the symptoms on functionality, co-morbid substance abuse, stigma and concerns over side effects (Haddad et al., 2014). Likewise, even when adhering to appropriate treatment regimens, pharmacological treatments are not effective for everyone, with a recent citation stating that between 20% - 60% of those with psychosis are regarded treatment resistant following pharmacological treatment (Howes et al., 2021). There are also clear drawbacks to pharmacological treatments, such as the side-effects associated with antipsychotic medication, which are perceived by those with psychosis. Some of those regarded treatment resistant to pharmacological interventions including those experiencing negative symptoms, are likely to benefit from PSI as part of their care (Lincoln and Peters, 2019), however these approaches do not work in all cases, with rates of attrition or non-compliance estimated at 13% (Villeneuve et al., 2010). It must be noted that whilst indicated as part of best practice (NICE, 2022), data from The Report of the National Audit of Schizophrenia found that across healthcare providers an average of one third (34%) of patients had not been offered this, (with variability between Trusts of those offered ranging between 0% and 94% (Royal College of Psychiatrists, 2012). The reasons for this may include service configuration and resource issues, such as lack of appropriately qualified personnel (Royal College of Psychiatrists, 2012).

2.9 Burden of psychosis

2.9.1 Global Incidence and Prevalence of Schizophrenia and psychotic disorders

A systematic review, based upon the findings of the global burden of disease survey, 2016, reviewed studies from 195 countries and territories worldwide, which reported on the incidence, prevalence and excess mortality associated with schizophrenia (Charlson et al., 2018). The outcome of the review was that the global (age-standardized) prevalence of schizophrenia in 2016 was estimated to be 0.28% (95% confidence interval [CI]: 0.24–0.31) and that the prevalence had risen from 13.1 million (95% CI: 11.6–14.8) in 1990 to 20.9 million (95% CI: 18.5–23.4) cases in 2016 (Charlson et al., 2018). This represented an increase of approximately 7 million individuals globally. A separate report from the United Kingdom: the ‘Adult Psychiatric Morbidity Survey cited the prevalence of psychosis at 0.7%, which was based on the presence of a psychotic disorder within the last year (McManus et al., 2016).

The incidence and prevalence of schizophrenia remains relatively low, its impact however is large in terms of health burden and reduced quality of life, with psychosis diagnosed as ‘schizophrenia’ contributing 13.4 million (95% CI: 9.9–16.7) years of life lived with disability to burden of disease globally (Charlson et al., 2018). According to the Global Burden of Disease Survey 2017, the burden of schizophrenia remains large and is increasing globally (He et al., 2020). The Age-Standardised Incidence Rate (ASIR) has fallen globally between 1990 and 2017 (Estimated Annual Percentage Change (EAPC) = -0.124; 95% CI = −0.114 to −0.135), however the Age-Standardised Rate of Disability Adjusted Life Years (ASDR) remains unchanged (He et al., 2020).

2.9.2 Impact on individual patients and their families from psychosis

One of the main reasons that this PhD has a focus on the treatment of psychosis over other conditions, is that psychosis can cause considerable distress, disability and burden to individuals and to their families and carers (Stanley and Shwetha, 2006). Symptoms can lead to a direct reduction upon quality of life alongside the negative repercussions of the stigma attached with an inability to function either in employment or socially, due to persistent symptoms and a lack of awareness within society (Nevarez-Flores et al., 2019). Unfortunately, the majority of patients with psychosis experience global and social dysfunction linked to a psychotic episode (Fulford et al., 2013), which persists after symptom remission (Velthorst et al., 2017). Dysfunction has become a key treatment outcome associated with psychosis (Figueira and Brissos, 2011).

Studies have specifically explored the experiences and views of those who have experienced psychosis. One study reports a cohort of individuals (n=69) presenting at mental health services who were categorised into ultra-high risk and non-ultra-high risk for psychosis (Heinze et al., 2018). Their levels of anxiety, depression and psychological distress were measured at baseline and then followed up at 3, 6 and 12 months, using a range of measures, including: Comprehensive Assessment of At Risk Mental State (CAARMS) (Yung et al., 2005), the Quick Inventory of Depressive Symptoms (QIDS) (Rush et al., 2003), the Overall Anxiety Severity and Impairment Scale (OASIS) (Campbell-Sills et al., 2009), the Kessler psychological distress scale (K-10) (Kessler et al., 2002) and perceived quality of life via the World Health Organization Quality of Life measure (WHO, 1993) (Heinze et al., 2018). Statistical analyses were conducted using mixed linear modelling, with group differences subject to the Bonferroni post-hoc test, and the results indicated that those with psychosis (n=14) experienced significantly more depressive symptoms based on analysis of QIDS scores (F (1 132.26) = 15.27, p < 0.001), greater anxiety based on OASIS score (F (2, 123.99) = 4.69, p = 0.011)), more psychological distress based on K-10 scores (F (2, 97.22) = 11.14; p < 0.001), and poorer quality of life, based on WHOQoL scores (F (2, 157.77) = 6.51, p = 0.002) between those who had and who had not experienced psychosis (Heinze et al., 2018). This finding indicates that patients with psychosis are more distressed, more depressed, and more anxious than patients with other mental health issues. Similarly, in addition to distress, people who have experienced psychosis (n=20) have described a perceived a sense of confusion and loss of their own personalities and a sense of self (Connell et al., 2015).

A meta-synthesis of 38 studies was conducted to explore the views of patients and carers on their respective experiences of the onset of psychosis symptoms, which represented the views of 378 patients and 176 relatives (Noiriel et al., 2020). The themes produced from the meta-synthesis of studies indicated that both patients and carers perceived the experience to be different, the traumagenic experience of psychosis for both patients and their care network were long-lasting and influenced their views on recovery (Noiriel et al., 2020). Balanced with this was the positive sense that familial relationships were strengthened through the treatment journey (Noiriel et al., 2020).

A systematic review and meta-analysis of the literature was conducted investigating the impact of psychosis on both employment outcomes and relationship outcomes (Ajnakina et al., 2021). Seventy-four studies were included with a total sample of 15272 (range=20-1724) cases of first episode psychosis, with a mean follow-up duration of 8.3 years (SD=7.2) (Ajnakina et al., 2021). The results of the meta-analysed data indicated that less than one third: 32.5% (95%CI=28.5-36.9) of people with a diagnosis of first episode psychosis disorders were employed and around one fifth: 21.3% (95%CI=16.5-27.1) were in a relationship at the end of their respective follow-up period (Ajnakina et al., 2021). It is clear, therefore, that whilst those with psychosis are keen to function in the same manner as those without psychosis, such as with a career and a functional relationship, however there are challenges to this, such as discrimination and a lack of support (Rinaldi et al., 2010). The impact of psychosis is that a smaller proportion of individuals are employed or have a functional relationship compared to the general population and psychosis creates psychological distress for those affected (Griffiths et al., 2019).

2.9.3 Views of the impact of psychosis from those with lived experience

People with psychosis report that they would like to live a life free from the stress associated with psychosis symptoms and aspire to have functional relationships, such as with a partner or spouse and having their own family (Parker, 2001). Furthermore, the aspirations of those with psychosis are the same as the general population in that they would like to own a house, a car and have a career that allows them to be self-sufficient (BGW, 2002; Ramsay et al., 2011). A systematic literature review of a series of first-person accounts of lived experience of psychosis and employment reported that despite a desire to find meaningful employment and even with the support of families, individuals are still met with low expectations from both family and professionals (Rinaldi et al., 2010). Additionally, caution and support are required for individuals due to the decision as to whether to disclose their mental health condition for fear of stigma and discrimination (Rinaldi et al., 2010).

2.9.4 Summary of the incidence and burden associated with psychosis

The incidence and prevalence of psychosis may be relatively low in comparison with other health conditions, however the burden associated with psychosis is great in terms of the impact on health systems through the treatment of symptoms and the associated co-morbidity, but moreover the impact is great on individuals who experience psychosis and their families. The evidence described in this sub-section also indicates that psychological distress and reduced quality of life are associated with psychosis and that this burden to individuals and their families persist despite treatment intervention. This is a clear indication from the findings of these studies that additional treatment strategies are warranted as part of psychosis management. This is also echoed within published reports from those with lived experience of psychosis.

2.10 The rationale for exploring diet intervention for psychosis management

This PhD is predicated upon the need to treat the symptoms of psychosis. As a Pragmatic inquiry, this PhD aims to answer a research question that is of value to those who experience it. Psychosis has been cited as one of the most life-impacting conditions in healthcare and one of the most significant in terms of long-term impact on lifelong outcomes and access to appropriate care (Ajnakina et al., 2021). Within the previous part of this chapter, a case has been built describing the nature of psychosis and its impact on individuals through the distress caused by symptoms and that current treatment approaches are not effective for all and include metabolic side-effects. This PhD is novel in that it seeks to explore the potential for diet as an intervention strategy for the management of psychosis. The following section therefore considers the role of diet in firstly the biological and secondly socio-cultural context of psychosis and then outlines key policy documents that have guided a role for diet in the management of psychosis.

2.11 The relationship between nutrients, the brain and psychosis

2.11.1 The brain’s requirement for nutrients

This PhD is examining the value of diet intervention for psychosis management. There is a clear biological rationale for this in that the brain is an organ which is formed from and maintained by nutrients sourced through the diet. The brain’s high demand for energy and nutrients is linked to its primary function, which is to control the body’s communication system through the process of neurotransmission (Benton, 2011). At rest, the brain uses 20% of the body’s energy requirement (Benton, 2011). Furthermore, the glucose, enzymes, vitamins and minerals necessary to produce and utilise that energy are sourced from the diet (Benton, 2011). Neurotransmission is the process by which brain cells, called neurons, communicate with each other and with other cells in the body via chemical impulses (neurotransmitters) (Gonzales and Jaworski, 1997). There has long been evidence that the quality of the diet can affect both the structure of the brain and the function of the brain (Wachs, 2000).

2.11.2 The role of nutrients in the formation and function of the neuron

Neurons are the brain’s cells which inter-communicate via neurotransmission, resulting in processes like thoughts and speech. Nutrients are essential for the successful formation and function of neurons in humans (Georgieff, 2007). Neuronal cell membranes are composed of a double layer of phospholipid, which is a structure composed of fatty acids. Within this phospholipid bilayer the most abundant fatty acids are omega-3 fatty acid Docosahexaenoic Acid (DHA) and the omega-6 fatty acid Arachidonic Acid (AA) (Peet and Williamson, 2011). These two fatty acids are required in a ratio of approximately between 1-2 AA: 1 DHA for optimal health benefit (Simopoulos, 2010). It is unclear to what extent these altered fatty acid ratios have on neurotransmission, however the levels of these fatty acids, especially DHA, in cell membranes have been found to be significantly lower in those with psychosis compared to the general population (Yao et al., 1994; Peet et al., 1995; Khan et al., 2002). Mechanisms for the reduced levels of these fatty acids in those with psychosis are not fully understood, however conjecture suggests abnormal metabolism (Peet and Williamson, 2011). This indicates a link between healthy brain cell structure and function and dietary sources of omega-3 fatty acids, which also supports the concept at the centre of this PhD, that there is value in exploring diet for psychosis symptom management.

2.11.3 The role of nutrition in the synthesis and uptake of Dopamine

As indicated earlier in this chapter (see Sections 2.4 and 2.5), those with psychosis are known to have sub-optimal dopamine neurotransmission (Kesby et al., 2018). This sub-section describes the key parts of the process of neurotransmission that are impacted by diet, specifically the synthesis of dopamine and the dopamine receptors located on the dendrites. The process of dopamine synthesis and function is another process central to psychosis manifestation that is highly dependent upon nutrition. Through the process of biosynthesis, the amino acid tyrosine is converted into the compound L-3,4-dihydroxyphenylalanine or ‘L-DOPA’ (Wykes et al., 1971). The neurotransmitter Dopamine is then synthesised from L-DOPA by the removal of a carboxyl group (Daubner et al., 2011). The presence of Tyrosine from dietary sources is therefore believed to affect the rate of dopamine production in other mammalian species (Choi et al., 2011), suggesting this may be the case for humans. Known food sources of dopamine is limited, potentially due to a prior lack of academic interest in the topic, however values exist for banana pulp (8µg/gram) and avocados (5µg/gram) (Briguglio et al. 2018).

In addition to tyrosine, other nutrients are required in the successful synthesis both within, and transfer of dopamine between, cells. Some micronutrients such as vitamin B3 (Hoffer and Prousky, 2008), vitamin B6 and vitamin B12 are also essential for dopamine production through acting as substrates for key enzymes required in its synthesis (Frazier et al., 2009). Trace elements (magnesium) are also essential for the maintenance of neurons, the movement of neurotransmitters (calcium) and the enzymatic processes involved in dopamine synthesis (zinc) (Demelash, 2017). Likewise, animal models have shown that an omega-3 deficient diet led to altered dopamine neurotransmission (Zimmer et al., 2000). In addition to the nutrients listed as essential to functional neurons and dopamine synthesis, glucose and Adenosine TriPhosphate (ATP), the body’s main sources of energy, are required at high concentrations for dopamine neurotransmission and neurons are the largest consumer of these in the brain (Ermakov et al., 2021). Animal models have also shown that a deficiency in iron reduces D2 receptor activity by 40-60% (Ashkenazi et al., 1982). The extent to which these animal models fully translate to humans is unknown, however the evidence provided in this section suggests a biological link between nutrients acquired through the diet and psychosis symptom modification. This therefore indicates that there may be potential value in exploring a diet intervention for psychosis management.

2.11.4 Nutrients that may alter neurotransmission

Thus far within this chapter, nutrients have been discussed in relation to their beneficial impact on dopamine neurotransmission, but there are nutrients and dietary components that may alter neurotransmission. One of these is caffeine, which upon digestion, is known to activate neurons and directly impact dopamine release (Nehlig et al., 1992), which for those affected by psychosis may increase the requirement for antipsychotic medication that works by blocking dopamine receptors (Broderick et al., 2005). Likewise, an alteration of dopamine neurotransmission has been reported in obese individuals (Wang et al., 2001). Animal models have demonstrated that excessive saturated fat and processed sugar intake can alter dopamine synthesis (Davis et al., 2008; Li et al., 2009) and that both the dopamine and opioid reward systems are downregulated (Reyes, 2012). This suggests that individuals feel the need to continue to overconsume saturated fat and processed sugar to reach their ‘reward’ or satisfaction point (Reyes, 2012).

In light of this, these nutrients are all especially noteworthy because caffeine, sugar and saturated fat for example, are consumed widely in the diet across the world and are consumed in excess (Public Health England, 2014; Reyes and Cornelis, 2018). Due to the need for nutrients in the optimal function of neurotransmitters like dopamine, there is an argument that diet is relevant to healthy neurotransmission and therefore diet intervention could support the management of psychosis symptoms.

2.11.5 Dietary sources of nutrients associated with dopamine neurotransmission

It is important to consider that nutrients are essential to human biology, but they are not consumed in isolation, they are sourced in complex combinations from an individual’s habitual food and beverage consumption. A definition of the term “diet”, as given by The Oxford Dictionary of English (2010) is as follows:

> *Diet: “The kinds of foods that a person, animal or community habitually eats”*
> *(Oxford Dictionary of English 2010, p.488)*

Both of these terms are relevant to the background of this PhD because individual nutrients can exert key, life sustaining functions within the brain and body, however the diet of an individual is where and how nutrients are sourced.

As described in the preceding sections, dopamine neurotransmission requires a range of nutrients for the formation, release and receipt of dopamine (Greenwood and Craig, 1987). The individual nutrients referred to in this thesis are habitually sourced from the diet through a range of complex combinations within the food and beverages we consume. The following table (Table 2.2) summarises principal dietary sources of some of the key nutrients involved in dopamine neurotransmission.

Table 2.2: Summary of principal dietary sources of key nutrients required for dopamine neurotransmission

Nutrient	**Use in brain**	**Dietary sources** (Department of Health, 2012)
Glucose	Energy requirement (Ermakov et al., 2021)	Carbohydrates from a range of whole grains, pulses, fruit, vegetables
Oemga-3 fatty acids	Formation and maintenance of neurons (Simopoulos, 2010)	Oily fish species, such as mackerel, herring and pilchards
Omega-6 fatty acids	Formation and maintenance of neurons (Simopoulos, 2010)	Seed oils, such as rapeseed oil, sunflower oil, eggs
Amino acid Tyrosine	Formation of dopamine (Wykes et al., 1971)	Egg, milk, fish, meat, lentils, bananas, nuts, pulses, spinach
Vitamins B3 (Niacin), B6 (Pyridoxine) and B12 (Cobalamin)	Substrate for the formation of key enzymes and conversion of food into glucose (Hoffer and Prousky, 2008; Frazier et al., 2009)	Vegetables, fruits, whole grains, pulses, beans, eggs, milk, yeast extract (marmite), meat
Minerals: Iron, Zinc, Calcium and Magnesium	(Ashkenazi et al., 1982; Demelash, 2017)	Fish, vegetables, fruits, whole grains, pulses, beans, eggs, milk, meat

2.11.6 Oxidative stress and the role of Antioxidant nutrients

Thus far within this chapter, the evidence linking diet and nutrition to psychosis has focussed on the neuromodulatory link with neurotransmission. There is also a hypothesised neuroprotective mechanism, linking diet to psychosis, which proposes that antioxidant nutrients may improve psychosis through reducing oxidative stress within the brain (Rambaud et al., 2022). Specific antioxidants cited include vitamins E and C and Polyunsaturated Fatty Acids (PUFA) (Ermakov et al., 2021). Oxidative stress has been associated with psychosis and is known to be harmful to health through inducing several chronic diseases and accelerating the ageing process (Pizzino et al., 2017). Measures of inflammation are raised, including C-Reactive Protein (CRP), which following meta-analysis (n= 8 within-group comparisons, n=713) was irrespective of pharmacological treatment with antipsychotic medication (g=0.01, 95% CI −0.20 to 0.22, P=0.803) (Fernandes et al., 2016). The findings presented in this section contend firstly that oxidative stress, which has detrimental effects on health in the long term (Pizzino et al., 2017), is an issue for those with psychosis. The antioxidant nutrients cited: vitamins E and C and PUFA are found in a range of foods, such as those listed in Table 2.2. There are therefore potential biological links between psychosis, oxidative stress and antioxidants sourced through the diet. This is further evidence suggesting that there may be value in exploring diet intervention for psychosis management.

2.11.7 Dietary intakes of the population are sub-optimal

2.11.7.1 Impact of food processing

This section thus far has considered the potential for the diet in supplying essential nutrients, it is important to note that whilst foods contain a range of nutrients, these are subject to variability within different types of foods, with the nutritional content of foods being affected by a range of factors such as production and processing techniques (Zheng and Xiao, 2022). The processing methods used to produce many of the foods we consume on a regular basis, are known to dramatically reduce the content of micronutrients, such as vitamins and minerals, for example (Reddy and Love, 1999; Zheng and Xiao, 2022). Processed foods are a staple in the diet of many individuals because they are highly palatable and are less expensive than whole food options (Weaver et al., 2014). As such, they contribute to food security for many countries, including the United States of America (Weaver et al., 2014). This ties in with a range of data collected as part of the United Kingdom National Diet and Nutrition Survey (years 1-4, combined), which indicated that the general population in the United Kingdom also eats a higher than recommended intake of highly processed foods and consequently a sub-optimal intake of micronutrients (Public Health England, 2014), including those add which ones listed in Table 2.2. This therefore represents an indicator that the wider dietary habits are not conducive to optimal neurotransmission processes.

2.12 Dietary habits of those with psychosis

In previous sections (see Sections 2.10 and 2.11) the case has been made for the role of nutrients, sourced through the diet, in impacting on brain function and thus on psychosis. A key part of exploring the value of diet for optimal brain function and psychosis management, must be to explore the nutrient intake and dietary habits of those with psychosis. This section explores the published evidence relating to the dietary habits of those with psychosis, including data pertaining to food groups, such as fruits and vegetables, also nutrient types, such as fat and protein and individual nutrients such as certain vitamins and minerals.

McCreadie et al. (2005) conducted an unblended randomised controlled trial with 102 individuals being allocated to receive either free fruit and vegetables for 6 months, or to continue with their habitual dietary intake with the aim of assessing the effect of fruit and vegetable consumption post-intervention. Participants in the intervention arm were also provided with information on the benefits of fruit and vegetable consumption and ideas and instructions on how to prepare the foods (McCreadie et al., 2005). Food consumption data was collected using the Scottish Health Survey Questionnaire and validated using blood samples to assess physiological status of micronutrients, showed that whilst there was an initial increase in fruit and vegetable intake, this had tailed off 12 months post-intervention (McCreadie et al., 2005). McCreadie and colleagues (2005) claimed that people with Schizophrenia made poor dietary choices following the intervention, despite receiving information and knowledge on the benefits of nutrition for their health. Another, more recent study of self reported intakes of different foods from patients with psychosis (n=397) found that just over half of respondents ate 3 or less portions of both fruit and vegetables per week (53% consuming ⩾3 fruit servings per week and 58% consuming ⩾3 vegetable servings per week) (Martland et al., 2023). These findings bear relevance to the research question at the centre of this PhD, which is exploring the value of diet for psychosis management. This is because the evidence indicates that dietary habits are not optimal and that even with written information, long-term dietary modification was unsuccessful for these individuals, indicating that strategies are warranted that support people with psychosis around their diet.

The dietary patterns of community-dwelling individuals with schizophrenia (n=88) were also mapped by Henderson and colleagues (2006) using 4-day food diaries. A comprehensive range of macronutrients and micronutrients were mapped including fat, protein, carbohydrate, fibre, sucrose, folate, calcium, sodium and zinc, in addition to cholesterol, alcohol and total energy intake (Henderson et al., 2006). The data were compared to the National Health and Nutrition Examination Survey (NHANES) results indicated that in all parameters the schizophrenia group consumed less than the United States national average, with the exception of caffeine, which was higher (Henderson et al., 2006). A study with 146 participants with schizophrenia also found no difference in energy intake, but also found a significantly higher caffeine intake of 471.6 mg versus 254.2 mg (471.6 ± 584.6 mg vs. 254.2 ± 384.9 mg, $t = 6.664$, $p < 0.001$) compared to the general population (Strassnig et al., 2006). A case-control study with fewer participants (n=23) indicated that there were considerably higher rates of dietary underreporting in females with schizophrenia (n=13; 77%, 95% CI:46–95%) compared to matched controls (N=10; 50%, 95% CI: 19–81%) (Khazaal et al., 2007), although this study was limited by its small sample size and that the sample comprised only female subjects, the findings warrant further, robust investigation.

A case-control study conducted with hospitalised patients diagnosed with schizophrenia and age-matched controls (n=30:30) reported that lower intake of a range of foods like fresh vegetables, fruit, nuts and chicken and higher full-fat cream and sugar-sweetened beverages than controls (Amani, 2007). An investigation of the intake of fatty acids and antioxidant nutrients was conducted in community-dwelling individuals with schizophrenia (Strassnig et al., 2005). The study found that intake of total Polyunsaturated Fatty Acids (PUFA) and saturated fatty acids (SFA) were higher in those with schizophrenia compared to study control, although no difference was found between groups in key omega 3 fatty acids: Eicosapentaenoic Acid (EPA) or DHA or for any of the antioxidant nutrients (Strassnig et al., 2005). No difference was found between the omega-3 fatty acid intake between the study population and the general population, but it is important to note that many individuals, particularly those in westernised countries are deficient in omega-3 fatty acid intake as demonstrated through blood concentrations (Stark et al., 2016). The dietary composition of men (n=56) and women (n=74) with schizophrenia with age, gender and ethnicity matched male (n=107) and female (n=143) controls has also been reported (Ratliff et al., 2012). The authors reported that there was no difference in energy intake between the two groups, however those with schizophrenia had poorer metabolic indices in comparison to the general population although portion sizes were larger (Ratliff et al., 2012). The validity of the findings from these two studies are limited through their use of only a single 24-hour dietary recall, as opposed to calculating a mean intake collected over several consecutive days, which is best practice for determining a more accurate picture of habitual dietary intake (Shim et al., 2014). These studies indicate that not only is the diet of those with psychosis potentially not optimal or conducive to support brain function, the diets of those with psychosis are potentially sub-standard to the general population, representing a larger gap between the nutrient requirement and nutrient intake of those with psychosis.

Further examples, relating to types of foods and not just nutrients, include a self-reported questionnaire-based study with a sample (n=159) or respondents all diagnosed with schizophrenia reported that a large proportion did not eat fish (63.1%) or did not consume fruit on a daily basis (40.8%) (Simonelli-Munoz et al., 2012). A study by Roick and colleagues (2007) concluded that those in the community (n=194) with schizophrenia in Germany ate more ‘snack’ foods and ‘instant meals’ compared to the population average, indicating that a higher proportion of the total energy consumed is from refined food and beverages, suggesting an unhealthy eating pattern (Roick et al., 2007). Data was collected more recently from a cohort of those with first episode psychosis (n=143) and the mean nutrient intake of the cohort was calculated following the self-completion of four-day food diaries and was then compared with the United Kingdom population average (Williamson et al., 2015). The results included a similar total energy consumption, but proportionately higher intake of non-milk extrinsic sugar compared with the U.K. average. Likewise, several of the micronutrients were lower than the national average; most notably selenium with over 50% of participants not meeting the lower reference nutrient intake (Williamson et al., 2015). The authors also reported that the diets consumed were high in refined, processed foods compared to the general population’s mean intake (Williamson et al., 2015).

A systematic review considering studies that had mapped the dietary intake of those with schizophrenia systematically searched health databases: Pubmed, The Cochrane Library Scopus, Embase, Ovid, PsychInfo and ISI Web of Knowledge and found 31 studies that met their inclusion criteria (Dipasquale et al. (2013). The review concluded that the diet of those with schizophrenia is poorer compared with the general population and was characterised by a higher intake of saturated fat and lower intake of fibre; the lower fibre intake was linked to a lower fruit intake (Dipasquale et al., 2013). The review was set in the context of assessing whether a poorer diet was then associated with poorer metabolic indices in patients, and it aimed to elucidate the factors that impacted upon this. The authors reported that those with schizophrenia had poorer metabolic indices, yet the factors affecting this were less clear and warranted further research (Dipasquale et al., 2013).

The diets of those with psychosis are generally less healthy than the general population with higher levels of ultra-processed foods, lower unrefined foods such as fruit and vegetables and consequently lower intakes of vitamins and minerals. The diets of those experiencing psychosis are poorer than the general population, which represents a potential deficit in nutritional quality because the diets of the general population are themselves often sub-optimal in terms of nutritional quality and the recommended consumption of key foods, such as fruit and vegetables. Based on the evidence of biological links between diet and psychosis and epidemiological data suggesting that the diets of those with psychosis are poor, dietary change strategies aimed at improving the diets of those with psychosis is warranted.

2.12.1 Section summary

The evidence presented in this section suggests that providing knowledge and support around food consumption may be warranted as a consequence of diminished global and social functioning linked to psychosis. The ubiquitous and unavoidable role that diet has within our culture and society and its fundamental role in sustaining life also adds strength to the rationale for conducting this PhD exploring the value of diet intervention for psychosis management. Following the evidence relating to biological links between diet and psychosis, the next section considers socio-cultural links between diet and psychosis.

2.13 The relationship between diet and the sociocultural aspects of psychosis

The previous section explored the links between certain nutrients and the biological processes that impact the manifestation and treatment of psychosis. Nutrients are habitually consumed through an individual’s diet and this section presents the societal, cultural and behavioural factors that indicate the value of exploring diet for the management of psychosis. This section considers the impact of psychosis on social and global functioning from a dietary perspective, the known difficulties with dietary behaviour change and evidence of the dietary habits of those with psychosis.

2.13.1 The role of diet within society

Diet as a representation of the both the preferred foods and beverages and the methods by which they are sought out, prepared and consumed is fundamental to the function of societies and cultures (Reddy and van Dam, 2020). Meals and different foods are also the hallmark of many religious ceremonies and certain foods are bound to rules and tenets listed in religious texts (Banta et al., 2018). Diet is also synonymous with family values across cultures, with family meals being a core example of family functioning (Miller et al., 2012).

Diet is viewed positively across many cultures as being a modifiable component to health behaviour for individuals (Rozin et al., 1999), such as a lower-fat diet (Byrne et al., 2016). In contrast to this however, diet is often perceived negatively by some in relation to health, with clear associations between the consumption of recommended healthy foods equating to a loss of pleasure (Cornil and Chandon, 2016). This negative connotation with diet is viewed both by individuals and wider society, as a representation by public health campaigns and the media, of the need to restrict food intake in the pursuit of health (Wahl et al., 2017). Despite the potential complex association between certain foods and health, mental health patients have expressed a preference for alternative treatment strategies, including diet and talking therapies over medication (Jorm et al., 2000). The consideration of diet as a treatment strategy similar to medication or psychotherapy would suggest that a transfer of knowledge from professionals to patients would be required. The perceived need for nutrition education in relation to mental health conditions has been explored with a sample of key stakeholders (n-39) ranging from university lecturers, nurses, social workers and patients and there was a consensus that a validated educational module should be available to healthcare practitioners to support patients with knowledge around diet (Clibbens and Williamson, 2016).

2.13.2 Challenges surrounding dietary change

In parallel to the complex and diverse relationships that individuals have with their diet behaviours, there exists a corresponding complexity when trying to change diet behaviours. The relationship people have with their diet is complex, starting in childhood through the development of habits, or through the use of food as a means of reward or punishment (Breakey, 1997). Importance has been placed on accepting the role of behaviour in food consumption patterns, particularly motivation and an individual’s readiness and willingness to change, aligned to appropriate behaviour change theory (Horwath et al., 1999). Behaviour change in relation to diet is complex and cannot be categorical as the consumption of food cannot be avoided unlike other behaviours, such as smoking (Shepherd, 2002). As a consequence of the complexity of diet and its fundamental role in the lives of individuals, behaviour change is difficult to implement at both the individual and population levels (Shepherd, 2002).

Evidence from a systematic review with 10 included studies of the efficacy of internet-based interventions promoting dietary change reported that interventions that reported using behaviour change strategies resulted in a significant, albeit small effect ($d+= 0.20$, $k = 10$; 95% CI: 0.02 to 0.37; $p<0.05$) versus those didn’t (Webb et al., 2010). One example of such behaviour change theories is the Transtheoretical model of change, which cites 5 stages related to health behaviour change, ranging from precontemplation through action and then maintenance (Prochaska, 2020). Individuals can cycle through these stages and will be impacted by a range of environmental and psychological factors, such as limited income, limited skills, stress or preference (Kris-Etherton et al., 2020). Diet behaviour is an important aspect to consider as part of a diet intervention aimed at effecting any health-related behaviour (Kris-Etherton et al., 2020).

One study reported on qualitative data collected from a series of focus groups (n=6 comprising 35 participants) exploring the perceptions of adults at risk of type-2 diabetes (Fukuoka et al., 2014). Findings indicated that barriers to healthy eating, including limited knowledge or finance, impacted on the success of dietary behaviour change, because behaviour change is bound by these contextual factors (Fukuoka et al., 2014). Contextual factors such as these, are of importance for ensuring the uptake and long-term feasibility of the intervention (Skivington et al., 2021). A successful diet intervention for psychosis management must be developed, or evaluated if already in existence, with key stakeholders' perspectives in mind.

2.13.3 Additional potential challenges surrounding diet intervention for those with psychosis

Previously within this chapter the central role that diet plays within society, cultures and daily functioning is apparent and the complex link between diet and improved health is clear in terms of the ability to effecting behaviour change. Psychosis may present additional challenges to this due to the impact of psychosis symptoms on social and global functioning as described previously in Section 2.9.2. An individual's ability to look after themselves is therefore disrupted in the presence of psychosis, particularly negative symptoms (Galderisi et al., 2018). The habits associated with food purchasing, preparation and consumption are intrinsic to individuals' global and social functioning and require a degree of planning, organisation, knowledge, concentration and resources (Fordyce, 2009). Social inclusion is known to be significantly reduced within individuals following psychotic illness and reduced social functioning in associated with reduced quality of life (Killaspy et al., 2014).

Consideration of an individual's circumstances goes beyond the practical elements to include factors such as support from a care network versus living alone, with data from a report published by the McManus et al. (2016) suggesting that living alone was twice as likely of developing psychosis, compared to those living with families or others. Living alone has also been associated with poorer dietary habits, including a reduced consumption of key food groups, such as fruits, vegetables and fish (Hanna and

Collins, 2015). Another commonality between psychosis and dietary habits relates to limited budget and low income. It is to be expected that people living with limited budgets will have poorer dietary habits (French et al., 2019). Data published in 2014 also suggested that adults aged 16-64 who were in receipt of government benefit were more likely to test positive for the presence of a psychotic disorder (7.2%), compared to those of the same age who were not (0.2%) (McManus et al., 2016). A potential association between low income and psychosis therefore may have repercussions on the quality of the diets consumed by people experiencing psychosis. The dietary habits of those experiencing psychosis are presented in the next sub-section.

2.14 Policy and guidance supporting diet intervention for psychosis management

This chapter has provided evidence and a case for the value in exploring diet for psychosis management, including the issues and inadequacy with current treatment options, the potential biological and social links between diet and psychosis. This section explores health policies and guidance that support the rationale to conduct this PhD exploring the value of diet for psychosis management. The inclusion of diet within healthcare policy or guidance for psychosis management is important because the implementation of a diet intervention would require support from the appropriate bodies responsible for healthcare provision, such as the Department of Health and Social Care. This section outlines a chronological overview and subsequent discussion of the published documents (see Table 2.3) that have, to date, indicated a role for diet in psychosis management and thus provide support for the conduct of is PhD.

Table 2.3: Overview of National guidance documents linking the importance of diet for mental health

Document title	**Year of Publication**	**Relevance to this PhD**
Choosing Health: Making healthy choices easier	2004	The U.K. government pledged to support public health communication campaigns tackling issues like smoking and obesity and they pledged to improve the mental health of the nation. One of the case studies presented within this chapter recommends a case study provided by Rethink (a mental health charity) that recommended that individuals with severe mental illness require dietary support due to the impact of symptoms

Document title	Year of Publication	Relevance to this PhD
		and the impact of psychotropic medication (Department of Health, 2004).
New Ways of Working for Psychiatrists	2005	Provided a clear recommendation to practicing clinicians to begin to embed dietary care into the treatment of severe mental illness (Department of Health, 2005a).
Associate Parliamentary Food and Health Forum report	2008	Made strong recommendations to the Department of Health that nutritional assessment and intervention should be provided as a standard part of care for those experiencing mental health problems (Associate Parliamentary Food and Health Forum, 2008)
National Health Service (NHS) Constitution	2012	Part of the NHS constitution is to delineate the set of principles by which the NHS operates, and the rights held by those accessing it. One of the rights relates to appropriate access to diet for all those accessing NHS services, which therefore includes those with psychosis: 'You have the right to receive suitable and nutritious food and hydration to sustain good health and wellbeing.' (Source: NHS Constitution for England; DHSC, 2021)
Five-year forward view for mental health	2016	This pledged to support innovation and research into new treatment approaches and new models of care and second, its mandate that developments in, and evaluation of, mental health care should include patients, carers and professionals' views (Mental Health Taskforce (2016)
Care Quality Indicator (CQUIN) on the provision of hospital food	2017	The aim of this Care Quality Indicator was to ensure 24-hour access for all users of NHS services to healthy and nourishing food, with a specific mandate to reduce the provision and promotion of foods high in fat, salt and sugar (NHS England, 2017)

The documents chosen for inclusion within this section underscore a recommendation to policy makers, responsible medical officers or a range a healthcare professionals that include that i) diet and the provision of sound nutrition is fundamental to health and patient choice within the NHS (NHS Constitution for England, DHSC, 2021), ii) Diet is linked to mental health (Choosing Health: Making Healthy choices (Department of Health, 2004), iii) Mental health services need to consider the dietary care needs of patients in a robust way (New Ways of working (Department of Health, 2005a); Associate Parliamentary Food and Health Forum report (2008) and iv) healthcare providers are encouraged through the avoidance of a financial penalty to both improve food access and reduce unhealthy food choices available to all users of the health system.

The first paper listed in Table 2.3 was a government white paper pledging to support public health campaigns to tackle health inequalities. It bears relevance to this PhD because it is the first publication by the U.K. government to suggest that diet is relevant to the health needs of those with severe mental illness. This was followed within a year by the Department of Health's report entitled 'New Ways of Working for Psychiatrists' (Department of Health, 2005a). This was a final report with national relevance for psychiatrists that was chaired by the Royal College of Psychiatrists and National Institute of Mental Health England (NIMHE). This best practice guideline was aimed at psychiatrists, who held the role of Responsible Medical Officers (RMOs) in mental health teams and according to The Medical Profession (Responsible Officers) Regulations 2010, have overall responsibility for the provision of care. This report is fundamental to the foundations of this PhD because this report produced jointly by health care professionals and a charity clearly advocated that diet had a role in the treatment of mental illness and it recommended that healthcare professionals consider the workforce and research requirements of providing dietary care as part of the treatment of severe mental illness (Department of Health, 2005a).

The Associate Parliamentary Food and Health Forum report, entitled 'The Links between Diet and Behaviour' (Associate Parliamentary Food and Health Forum, 2008) is similar to the New Ways of Working for Psychiatrists document (Department of Health, 2005a) in that it is not a policy or a mandate. It also makes strong and clear recommendation to the Department of Health that nutritional assessment and intervention should be provided as a standard part of mental health care (Associate Parliamentary Food and Health Forum, 2008).

The NHS Constitution (DHSC, 2021) cites the importance of the access for patients of sufficient nutritious food and fluids to promote health and wellbeing. This is noteworthy for two main reasons, firstly because the NHS constitution was developed following consultation with patients and members of the public and secondly because this document underpins the care provided to all patients in all NHS services. Not all commissioned services caring for those with psychosis in the U.K. are operated within the NHS and of course internationally there is a variation in the standards of care provided for the management of psychosis. More recently, NHS England developed a Care Quality Indicator (CQUIN), which pushed for a clearer mandate for health service providers to provide 24-hour access to healthy and nourishing food to all users of their services, including patients, carers and staff (NHS England, 2017). The mandate supported the implementation of healthy choices for patients, carers and staff through suggesting a ban on the promotion of foods high in fat, salt and/or sugar, going as far as imposing financial penalties for Trusts that exceeded the targets (NHS England, 2017). The development and implementation of the CQUIN strongly suggests that there is increasing value being placed by policy makers on diet and the provision of nutritious food as a core component of general health.

Despite these clear recommendations to policy makers and commissioners over almost the last two decades, dietary intervention is not embedded in clinical practice or service delivery models for all patients with psychosis. It is likely that any diet discussions with patients would be informally done by an HCP, perhaps as part of a physical health assessment. It is unclear why this hasn’t been embedded more fully in care pathways.

This sub-section has summarised the key policy documents that clearly suggest that policy makers and those setting developing health service guidance agree that diet is important for mental health. These policy or guidance documents provide further justification for conducting this PhD, which seeks to explore the value of diet intervention for psychosis management.

2.14.1 Summary of the potential role of diet in the management of psychosis

The exploration of the value of diet as an intervention to manage psychosis in this Pragmatic, mixed-methods PhD is built around the knowledge that diet is the principal source of all nutrients, which impact the function of the brain. Furthermore, it is built upon the role that diet has, which goes beyond meeting the physiological requirements of the brain and is at the heart of societies and cultures. A basic knowledge of food and nutrition and possession of key skills on basic meal preparation are a required part of a healthy diet. Increasing the knowledge of diet and brain function in relation to mental health conditions, such as psychosis would be welcomed to support behaviour change toward an optimal diet (Clibbens and Williamson, 2016), thus leading to a brain with improved function. This PhD inquiry is not exploring the value of diet for psychosis management as a ‘competitor’, or alternative to existing treatments, such as pharmaceutical or psychosocial. If diet intervention for psychosis does have value, then this adjunctive strand of care may improve brain function and thus may have additional benefits for other treatment options, such as accelerating the uptake of psychosocial interventions and/or exerting a medication-sparing effect on prescribed antipsychotics.

2.15 Chapter Summary

This chapter represents the background literature relevant to this PhD and begins with a description of psychosis, outlining its features, the contributory factors to its manifestation and current treatment strategies. The manifestation of psychosis arises a sub-optimal brain function, which is normally treated with pharmacological and psychological intervention. This PhD aims to explore the concept that diet may be utilised as an additional treatment option for psychosis management. The rationale for this is partly because despite psychosis treatment strategies having advanced significantly over the last six or seven decades, there remain individuals who do not respond to treatment. This issue is further exacerbated by a high rate of non-adherence to treatment strategies and the adverse impact from a range of metabolic side effects associated with pharmacological treatment of symptoms.

Diet, or nutrition, seems a logical choice in the management of psychosis firstly because several nutrients are essential to the biological processes within the brain. Particularly neurotransmission, which is altered in those with psychosis and forms the basis of current pharmacological treatments. A second reason to consider dietary support for psychosis management is that published evidence indicates that the major source of nutrients is the diet, which is sub-optimal in both the general population and more so for those with psychosis. Diets are potentially lacking in the nutrients essential for healthy brain function, whilst containing excessive nutrients and other components that are known to adversely impact on mental health.

To summarise the need for this inquiry, there is compelling evidence around the link between nutrients and the diet with the brain and its role in psychosis. There is less evidence on what a dietary intervention would entail or how it would be structured, despite clear indication from stakeholders that increased knowledge on diet and mental health would be welcomed (Clibbens and Williamson, 2016). This concept is backed by documents, such as the New Ways of Working for Psychiatrists report (DoH, 2005a) and a Parliamentary report into the links between diet and behaviour (Associate Parliamentary Food and Health Forum, 2008). There is however a need to understand the format and method of delivery for dietary assessment and intervention for individuals. An inquiry that would determine the best method(s) for assessing the nutritional status and addressing those needs of individuals is warranted.

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3. THEORETICAL METHODS

This chapter details the epistemological, ontological, axiological and then methodological underpinnings of this PhD, which aimed to explore the value of diet intervention for psychosis management. As part of the exploration of a diet intervention for those affected by psychosis, the Pragmatically rooted PhD is aligned with a published practical guideline for the development, implementation and evaluation of complex healthcare interventions: The Medical Research Council's (MRC) Guidance for the development of complex interventions (Skivington et al., 2021). This guidance document was a useful framework for the conduct of this PhD because it too cites an approach aligned to Pragmatism through its recommendation to utilise methods that understand what works and in which contexts (Skivington et al., 2021). The examples of this within this PhD include conducting a systematic review of peer-reviewed findings from RCTs that have tested diet interventions with regard to psychosis management and the collection of primary data through meaningful engagement with healthcare professionals (HCPs), Patients and Carers as key stakeholders involved with psychosis management.

3.1 History of the Philosophical underpinnings of Healthcare Research

For centuries philosophers have pondered the meaning of existence, what constitutes knowledge and the concept of 'truth'. A desire for an advancement of knowledge has occurred in parallel to this. This PhD seeks to advance knowledge in the fields of mental health care, specifically psychosis, through consideration of the potential value of diet as an intervention. The consideration of diet for its benefit to health is not new. Bhatt (2010) refers to an early account within the Bible as early as 562 BC of a comparison between two diet-related variables in relation to their impact on health. This Biblical comparison involved some individuals within that population eating a diet rich in meat, whereas others were allowed to continue to consume a vegetarian diet over a period of 10 days (Bhatt, 2010). The outcome of this early trial was that those consuming only vegetables appeared to be better nourished and thus a decision was taken in the Kingdom that people were allowed to continue a diet free of meat for the benefit of their health (Bhatt, 2010). Following that uncontrolled trial to the World's first published Randomised Controlled Trial (RCT) examining the efficacy of treatments for Scurvy (circa 1753), there has been great progress in the field of medical research leading to global advances in healthcare. Underpinning the advances in research methods, there have also been advances in the philosophical debates centred around both what constitutes 'knowledge' and what constitutes 'reality'. Creswell and Creswell (2018) contend that individuals have a set of beliefs, which they deem to be: "*a general* *philosophical orientation about the world and the nature of research that a researcher brings to a study*" (Creswell and Creswell, 2018, pp44).

3.2 Paradigms in Healthcare Research

The philosophical underpinnings of research in healthcare are very important as they shape the nature and direction of the research that is to be undertaken (Creswell and Creswell, 2018). These have been labelled philosophical 'worldviews' by some because they relate to the respective belief system that guides action (Creswell and Creswell, 2018) and 'paradigms' by others (Anand et al., 2020). The term Paradigm describes the overarching philosophical stance and the inherent set of beliefs within that stance, that when applied, facilitate the generation of knowledge (Rubin and Rubin, 2005). There are several different paradigms that guide health-related research studies, each with their own philosophical assumptions that form the basis of research studies. These include: Positivism/Post-positivism, Interpretivism/Constructivism and Pragmatism (Cresswell and Cresswell, 2018). Each paradigm provides a different perspective on core philosophical assumptions, including axiology (what is valued), ontology (theory of being or reality), epistemology (theory of knowledge) and methodology (the chosen discipline of research) (Kaushik and Walsh, 2019).

3.3 Paradigms in the context of this PhD

The main paradigms tend to differ based upon their fundamental views of epistemology, ontology, axiology and therefore methodologies required to answer a given research question. In summary, these paradigms either support a solely theory testing (positivist) or theory generation (interpretivist) approach or a combined approach (pragmatist) to answering a research question. An overview of these three approaches is provided in this chapter to add context and justification of the theoretical methods underpinning this PhD.

3.3.1 Theory testing: Positivism and Post-positivism – 'Quantitative' research methodological approach

The positivist approach, first described by Comte in the 18th Century (Creswell and Creswell, 2018, pp44) seeks to determine the general laws and objective facts present in the natural world (Allsopp, 2013). Positivism seeks to discover cause and effect relationships and aims to provide explanations of a phenomenon and make predictions based on measurable outcomes (Kivunja and Kuyini, 2017). This paradigm cites that the role of the researcher is such that they can (and should) stand apart from the phenomenon being investigated in order to observe it objectively (Kane and O'Reilly-De Bruin, 2001). Positivism was historically the approach synonymous with healthcare research, however it has been criticised through failing to account for the impact of context and human experience (Fox, 2008).

Post-positivism emerged in the 20th century as a rejection of positivism (Clark, 1998). The post-positivist researcher believes that observations cannot be relied upon because they are imperfect and subject to error (Young and Ryan, 2020). Post-positivism is an objectivist deductive approach to research and views that the observer is never truly objective and will be biased based upon their own worldview (Varpio et al., 2021). It is clear that whilst post-positivism notes the potential for error and bias, and thus considers that universal truths are unattainable, post-positivist researchers believe that the production of a wholly universal truth is not necessary to advance knowledge (Young and Ryan, 2020).

This PhD seeks to understand the value of diet intervention for the management of psychosis. A post-positivist stance could have been selected to guide the first part of this PhD, specifically the systematic review of published literature reporting the efficacy of diet interventions for the management of psychosis, however relying solely on outcomes generated related to the quantification of what works, would fail to account for the subjective context(s) in which the trialled intervention works for the intended population. Contextual factors, such as timing, location and preference have long been identified as important aspects of healthcare interventions (Brennan and Strombom, 1998). Gaining an understanding of the context and meaning from stakeholders remains an important as part of a successful complex healthcare intervention by the MRC (Skivington et al., 2021).

3.3.2 Theory generation: Interpretivism/Constructivism - Qualitative methodological approach

The second paradigmatic approach that was considered and rejected as part of this PhD is the Interpretivist and Constructivist worldviews, which are often described together as one paradigm, as they are closely linked (Gray, 2018). Researchers working within both Interpretivism and Constructivism endeavour to understand and value human experience, which is inherently subjective (Kivunja and Kuyini, 2017). Interpretivism is driven ontologically by the subjectivism of reality and that what we know cannot and should not be tested against objective criteria (Gray, 2018), it instead should be constructed through applying meaning to experience (Fox, 2008). In essence, the interpretivist assigns and constructs names to interpreted findings (van der Walt, 2020). To that end, interpretivism uses a range of well-defined ‘qualitative’ research methods, which are designed to explore and collect data from the viewpoint of the subject(s) being observed, as opposed to the viewpoint of the observer (Kivunja and Kuyini, 2017). These techniques have successfully been utilised in healthcare research for decades (Pope and Mays, 1995).

Within this worldview, the axiological position is values-bound and one where the researcher should make sense of the data through their own cognitive processing, following their interactions with participants' epistemology (Kivunja and Kuyini, 2017). This paradigm assumes a relativist ontology and balanced axiology, whereby multiple realities exist and reality is constructed following researcher and participant interaction(s), all underpinned by the morals and values of the researcher (Kivunja and Kuyini, 2017). The outcome of qualitative research is to generate theories based on the data collected, as opposed to the positivist and post-positivist approaches, which commence with theory generation or hypothesis development that they seek to test (Creswell and Creswell, 2018).

The Interpretivist paradigm was rejected as the approach for this PhD because it could not have guided the totality of the inquiry. It could not, for example, advise on the efficacy of any previously trialled interventions that were published in the literature against the outcome of interest: psychosis symptoms. The value of the outcomes of trialled diet interventions in answering the research question would require objective scrutiny using quantitative methods, such as meta-analysis of published trial data.

3.3.3 Positivism and Interpretivism as competing approaches

These two approaches have traditionally been pitched as opposites (Pope and Mays, 1995), however, Pragmatism is one paradigm that seeks to reconcile these different approaches (Maarouf, 2019). At the outset of this PhD journey, it was clear that the exploration of the value of providing a diet intervention for psychosis management, would require the use of both a quantitative approach (at the outset to identify any existing interventions that has been subject to RCT methodology) and a qualitative approach (to explore the contextual factors related either to the implementation of any trialled interventions which were identified from the systematic review, or the development of a diet intervention that could be implemented). Thus, a Pragmatist worldview, which views knowledge as being present on a continuum and utilises mixed methodological approaches to generate knowledge, would be required to best answer the research question. This is because a wholly positivist or a wholly constructivist stance would be naïve and ineffective in terms of producing a robust intervention. For that reason, Pragmatism is the paradigm underpinning this thesis.

3.3.4 Pragmatism - Mixed Methods Methodological approach

It may seem counter-intuitive to suggest that two approaches that have traditionally been considered poles apart (Pope and Mays, 1995), could successfully be combined practically and philosophically. At its heart, however, Pragmatism firstly considers practical application to be the bedrock and the test of knowledge; and secondly that knowledge is judged according to its consequences in action (Cornish and Gillespie, 2009). Pragmatism is driven by the pursuit of actionable knowledge, which is contextually relevant (Kelly and Cordeiro, 2020). Inherent to Pragmatism is the sense that knowledge and action are interconnected and that the knowledge and belief system of a person cannot be separated from the context in which they are viewed (Carlsen and Mantere, 2007).

Pragmatism's roots lie in the United States over a century ago with the philosophers Charles Sanders Peirce, William James, John Dewey and George Herbert Mead (Cornish and Gillespie, 2009). At the time when Pragmatism was first conceived as a paradigm for social research, inquiry in the field of healthcare was centred on the positivist pursuit of gaining objectifiable, data-driven knowledge. Pragmatism thus evolved as a response to an academic scepticism of the existence of the 'perfect' or 'true' knowledge which governed positivism (Ormerod, 2006). Peirce believed that thought led to beliefs, which were the motivators for an individual to act and that the meaning of any idea was an indistinguishable part of the experience that formed it (Peirce, 1998). James developed Peirce's working definition to include the importance of the subjective elements that influence experience, such as understanding a person's thought processes and how that influences how their reality is constructed (James, 2010). Dewey's approach to Pragmatism was to acknowledge that human experience, either individual or shared, required interpretation (Dewey, 1922). Knowledge gained through the interpretation of human experience leads to action, which in turn leads to reflection and then new knowledge and actions (Morgan, 2014).

Pragmatism underpins this PhD. The first reason for this is that the aim of this PhD is the pursuit of a diet intervention (an action providing value) that could be delivered in addition to existing treatments and lead to improvements in psychosis management. The second reason is that the values of the researcher are closely aligned to Pragmatism. The advantage of a Pragmatic approach is the use of a combination of methods to allow examination of a phenomenon from a range of different viewpoints. This should provide datasets that are complementary and strengthen the quality of knowledge produced in relation to the research question (Maarouf, 2019). A further advantage is the legitimised use of triangulation, a method whereby the results sourced through different research methods and seen from different viewpoints can be combined to strengthen the overall findings of an inquiry (Farmer et al., 2006).

3.4 Research Designs inherent to Pragmatism

There are three main research designs inherent to Pragmatism according to Creswell and Plano Clark (2017), which are:

1) The Convergent Parallel Mixed Method (Using both quantitative and qualitative methods simultaneously)
2) The Explanatory sequential Mixed Method (Using quantitative method first and confirming or exploring further with the use of qualitative method(s))
3) The Exploratory sequential Mixed Method (Using qualitative method(s) and then confirming the theory/ies generated through testing with the use of quantitative method(s))

When exploring the value of a diet-related intervention to manage psychosis, the first step would logically be to consider published evidence of 'what had worked' and thus use quantitative methodological approaches. Examples of this approach include the meta-analyses of previously published randomised controlled trials (RCTs) against relevant outcome measures, such as effect on psychosis symptoms. The next logical step would be to apply context and meaning to the meta-analyses' results with an exploratory study which used qualitative methods. To that end, an explanatory sequential mixed method design was used for the conduct of this study (See Figure 1).

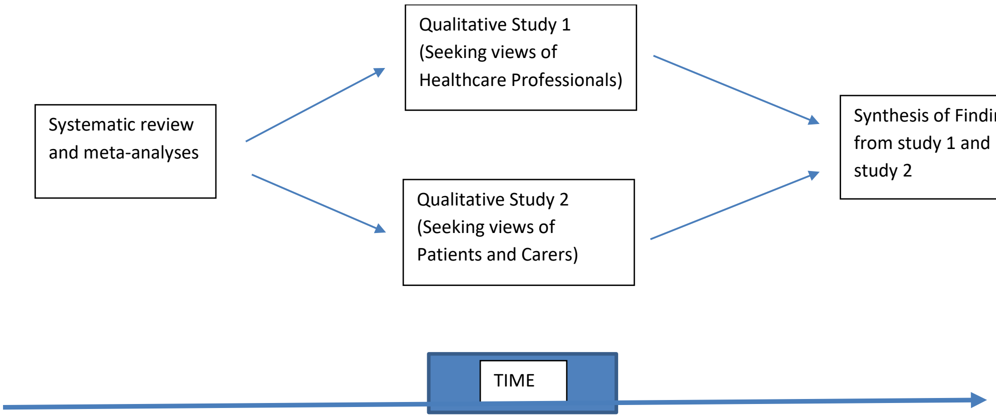

Figure 1: Explanatory Sequential Mixed Methods design of this PhD

3.4.1 Three philosophical approaches inherent to Pragmatism

Since the emergence and application of Pragmatism as a paradigm associated with mixed methods research, it has faced criticism for failing to have a strong philosophical underpinning (Biddle and Schafft, 2015; Kaushik and Walsh, 2019; Maarouf, 2019). In response to this, proponents of the value of mixed methods research have outlined three predominating philosophical approaches associated with the conduct and defence of mixed methods research (Hall, 2013), which are:

1) The a-paradigmatic stance
2) The multiple paradigm approach
3) The single paradigm approach

The first approach fails to acknowledge that research is underpinned by a philosophical worldview and the second approach seeks to align the research to the paradigm closest to the chosen method (Hall, 2013). Weber (2004) advocated this approach by reporting the view that comparing and contrasting the paradigms was unhelpful, as high-quality research conducted by excellent researchers should be matching the methods that best suited the objectives of their inquiry. Critics of the first two approaches are aligned to the third, which considers a singular approach to mixed methods research with a distinct epistemological, ontological, axiological and methodological viewpoint (Maarouf, 2019). One issue has been, however, that whilst the methodological viewpoint (the use of a combination of methods) and the epistemological viewpoint (the pursuit of actionable knowledge) is clear, there is less clarity on the ontological and axiological viewpoints (Maarouf, 2019). This PhD is rooted in the third approach and the following sections will describe the epistemological, ontological, axiological and methodological approaches used within the conduct of this PhD.

3.4.2 Epistemological approach in this PhD

Epistemology is a term that describes how we acquire knowledge and the relationship between the 'knower' (researcher in this case) and the 'known' (research) (Creswell and Creswell, 2018). Pragmatism's epistemological position is that knowledge is unique to an individual because it is nuanced and shaped by their experiences (Kaushik and Walsh, 2019). In Pragmatism, there is the pursuit of 'actionable' knowledge, which is knowledge that has value in improving one's existence (Goldkuhl, 2012). The epistemological position of actionable knowledge has also recently been subject to clarification through a concept termed "double-faced knowledge" (Maarouf, 2019). This concept involves consideration of what is observable and what is unobservable knowledge located on a continuum. This is pertinent in health and sociological research for example, because it could be argued that knowledge is never truly observable or unobservable. The Pragmatic researcher will therefore work within the continuum between what is observable and what is unobservable, and will therefore utilise the methodological approach(es), considered most appropriate to answer a given research question. This potentially reconciles some of the prior criticisms of Pragmatism as lacking in philosophical clarity.

This PhD starts with a systematic review of what is ‘known’ (observable knowledge) in terms of the efficacy of diet interventions for psychosis management. Following the outcome of that review, the subsequent phases of this PhD seek to know what key stakeholders know and think (unobservable knowledge) about a diet intervention for psychosis management.

3.4.3 Ontological approach in this PhD

Ontology is the nature of reality and Pragmatists have concluded that reality can never truly be determined (Pansiri, 2005) and that the broader philosophical arguments can never be solved (Kaushik and Walsh, 2019). Pragmatism in concerned with the nature of experience, as opposed to the nature of reality and Pragmatists believe that no two people have identical experiences, although there will be overlaps and commonality (Kaushik and Walsh, 2019). Pragmatists contend that any phenomenon should be examined from more than one perspective to get a more thorough understanding of its reality (Maarouf, 2019). This is because any reality is neither wholly objective nor wholly subjective because it is dependent upon the experience and perception by individuals (Kaushik and Walsh, 2019). Objectivism and subjectivism should therefore not be considered as being in competition, with both being equally valid and important in research inquiry (Maarouf, 2019) and will add to its value (Kaushik and Walsh, 2019).

Objectivity and subjectivity have been viewed as representing different points on a continuum (Maroouf, 2019). Maarouf (2019) expands on the objectivity-subjectivity continuum, with the concept that one reality exists (objective), but that there are multiple perceptions of that reality (subjective), which they have expounded into what they term ‘The Reality Cycle’. The Reality Cycle contends that 1) reality is impacted upon by individuals’ perception, which then leads to 2) a change in behaviour for individuals, which then 3) impacts on the context of the reality for each individual, which then 4) impacts on reality (Maarouf, 2019). This theory considers that whilst the reality cycle is ever revolving, a change in reality is likely to be slow and thus reality is relatively constant (Maarouf, 2019). It also clearly indicates the concept of multiple realities through the different perceptions (as viewed through the different lenses) of individuals (Maarouf, 2019). The reality cycle allows the pragmatist to articulate that whilstever reality is relatively stable, a theory can be generated and tested using objectivist, quantitative methods, in order to provide knowledge about ‘what works’, whilst the cycle can also allow the researcher to understand that when the context changes, a subjective, qualitative exploration is required to review current (existing) theories and generate new ones, if required (Maarouf, 2019).

The Reality Cycle therefore contends that there is one reality with multiple perceptions of that reality, which are all dependent upon contextual factors. The MRC Framework for the development of complex interventions also places importance on contextual factors as influencers in the acceptability and potential success of healthcare interventions (Skivington et al., 2021). The ontological view within this PhD is that ascertaining the effect of previously trialled diet interventions on psychosis symptoms is important, but of equal importance is the perception of the experience and contextual factors of those receiving or delivering a diet intervention for psychosis management. The analysis of these data helped to provide contextual factors that are relevant in providing answers to the PhD question.

3.4.4 Axiological approach in this PhD

Axiology is defined as the values and ethical considerations that form part of a research inquiry and Pragmatism hasn't always had a clear axiological framework (Biddle and Schafft, 2015). In axiological terms, Pragmatism is bound by the concept of adding value by conducting research to determine 'what works', however it has been criticised for not always determining what works for who (Biddle and Schafft, 2015). It must be acknowledged that values and bias exert influence to a certain degree, because the phenomenon of interest exists prior to a healthcare research inquiry, unlike in the natural sciences (Saunders et al., 2009). It is for this reason that Pragmatism aligns to a viewpoint that there is no potential for bias-free or values-free research in health and the social sciences and thus should be conducted with the least bias necessary, which has been referred to as 'The Necessary Bias Principle' (Maarouf, 2019). A desire to seek the views of those who would be delivering and receiving a diet intervention for psychosis management indicates an axiological position of the PhD researcher as firstly seeking to improve the lives of those with psychosis, and secondly as achieving this through engagement and seeking their views as part of the development of a diet intervention.

3.4.5 Associated Theoretical underpinnings of this PhD

The theoretical basis of this PhD is rooted in Pragmatism, which allows the researcher to conduct action-led research, using robust methods, to support the development of a complex healthcare intervention. Alongside the theoretical underpinnings of this PhD, sat the need to consider any published guidance on the theoretical development or implementation of complex interventions that are to be delivered in healthcare settings. The Medical Research Council (MRC) originally developed and published a guidance framework to streamline or systematise the way that complex healthcare interventions are developed and evaluated (Campbell et al., 2000, updated: Craig et al., 2008) with the most recent revision published during the conduct of this PhD (MRC, 2021). The framework defined a ‘complex’ intervention as one comprising several interacting components and one in which certain sensitivities, such as local context, logistical difficulties and organisational factors may be critical in influencing the outcome (Skivington et al., 2021). The guidance therefore provides a systematic approach for the development of new interventions, whilst taking account of factors including complex settings, behaviours and interactions between these factors (Skivington et al., 2021).

The systematic approach suggests that the process should commence with evidence synthesis to understand what has been tried and whether it works, which should sit alongside meaningful engagement with key stakeholders throughout the process (Skivington et al., 2021). Evidence synthesis is required to understand whether an intervention exists that can be either evaluated or refined, or whether there is insufficient evidence to recommend an intervention, thus indicating that one should be developed. The updated guidance document (Skivington et al., 2021) very clearly aligns to a Pragmatist explanatory sequential approach because it indicates firstly that objective knowledge is helpful, such as to determine the value of previously developed interventions against clear outcomes, but meanwhile that this knowledge must only be considered meaningful alongside an understanding of the context and perception of key stakeholders experiencing the intervention (Skivington et al., 2021). Furthermore, the guidance itself was developed not from a wholly theoretical perspective, but fundamentally due to the need for the systematised production of actionable knowledge - of ‘what works’ - in terms of the components or requirements of an intervention for a given population within the context that would bring about a positive behaviour change (Skivington et al., 2021). Furthermore, the guidance therefore clearly advocates the use of a mixed-methods approach to generate that knowledge (Skivington et al., 2021).

3.5 Application of the MRC Framework in the context of this inquiry

There is evidence from the Background chapter (Chapter 2) of biological, social and cultural links between diet and psychosis, combined with evidence that dietary habits of those with psychosis have been described as sub-optimal (See Chapter 2, Section 2.12). Based upon the evidence given in the background chapter (Chapter 2) there is potential value in diet intervention for psychosis management and the focus of this PhD is the development of a diet intervention for psychosis management. This inquiry was conducted to answer the following research question:

> *“Is there value in providing a diet intervention for the management of psychosis?’*

The consumption of nutrients through diet and the factors affecting dietary choices are multi-factorial and those experiencing psychosis may live or stay in a range of environments, such as in hospital and in the community, so a diet-related intervention for those who are experiencing, or have experienced, psychosis meets the MRC’s criteria for a complex intervention (Skivington et al., 2021).

The Framework describes five distinct phases in the process of developing and implementing a complex healthcare intervention: developing, piloting, evaluating, reporting and implementing (Skivington et al., 2021). The guidance cautions against heavy focus on the main evaluation phase, citing that the early development and piloting phases are important to ensure a strong foundation (Skivington et al., 2021). For the purposes of this PhD, it was unclear at which phase the inquiry would be focussed due to a lack of knowledge whether an intervention existed or whether there was a need to develop one. Secondly, it was unclear at the outset how far through the 5-staged process this inquiry would progress, but as directed by the guidance, the inquiry started with a review of the existing literature and following the outcome of that as part of the development phase.

The development phase (Skivington et al., 2021) comprises three distinct steps, which are essential to provide an intervention’s solid foundation. Following the Pragmatic worldview and within the practical bounds of this PhD, such as the allotted timeframe, steps one and two were completed as part of this PhD, as described in Figure 2.

Step 1	Step 2	Step 3
Identifying the evidence base	**Identifying/developing appropriate theory**	**Modelling process and outcomes**
Delivered as part of the PhD	Delivered as part of the PhD	Not delivered as part of the PhD
• Source and locate relevant evidence base	• Understand the relevant theory relating to the proposed intervention	• Conduct a pre-trial economic evaluation to test the benefits of the intervention v the cost prior to launching a full-scale implementation
• Conduct a systematic review/meta-analysis(es) of the evidence, unless a recent one has been completed	• Support theory development through the presentation of findings and discussion from additional data collection, such as conducting ‘stakeholder’ interviews of individuals involved in delivering or receiving the intervention to explore the contextual factors influencing the development and implementation of any intervention	• Determine who needs to know the outcome of the small-scale intervention and determine what information they require

Figure 2: Application of the MRC Framework in the completion of this PhD (Adapted from Skivington et al., 2021)

3.6 Development Phase – Step 1: ‘identifying the evidence base’ through Systematic Review of published literature

3.6.1 Choice of review methodology

Traditionally, a systematic review potentially comprising a meta-analysis of published Randomised Controlled Trials (RCTs), where sufficient data permits, was cited as the gold standard for healthcare intervention evidence syntheses (Hariton and Locascio, 2018). There are other systematic review methods that include the review and potential meta-synthesis of qualitative studies and Grant and Booth (2009) discussed 14 main review types and contrasted the key characteristics, advantages and disadvantages of these, with examples including scoping review, narrative review and systematic review methodologies.

Scoping reviews are broad both in terms of the methodological approaches of included studies and the type of publication and thus permit the inclusion of conference abstracts, dissertations or peer-reviewed journals (Grant and Booth, 2009). A scoping review of the literature could identify attempts at the development of a diet intervention for psychosis management, however these interventions may not have been robustly compared for efficacy against standard treatment. A narrative review, for example, could also provide a good description of interventions that have been developed, however these methods would not be appropriate to answer the research question at the centre of this PhD because the research question relates to “the management of psychosis” and thus requires the assessment of the efficacy of the intervention versus traditional care on psychosis symptoms. This is through their intrinsic remit to exhaustively search and appraise relevant literature (Hartling et al., 2009; Grant and Booth, 2009). The Cochrane Handbook (2011) for conducting systematic reviews of interventions describes it as:

> *‘collate all evidence that fits pre-specified eligibility criteria in order to address a specific research question... systematic reviews aim to minimise bias by using explicit systematic methods’* (Higgins and Green, 2011).

The MRC Guidance indicates that a systematic review of the appropriate published evidence is required (Skivington et al., 2021). The choice of method for a systematic review of the literature is dependent on the aim of the review and thus how best to answer the review question (Grant and Booth, 2009). As this PhD sought to ascertain actionable knowledge that is contextually relevant, it seemed prudent that any newly developed intervention should have been tested within the given population (those experiencing psychosis) and evaluated objectively against standard treatment in relation to psychosis symptoms. A systematic review of the literature was therefore considered the best review methodology for this PhD because systematic reviews are the most comprehensive method of determining whether an intervention provided benefit over standard care.

3.6.2 Defining the review question and search strategy

The review question was developed using the Population, Intervention, Comparison, Outcome and Study Design (PICOS) framework (Sackett et al., 1996), as described in Table 3.1. The framework recommends that clinical questions should be framed to include details of the population under investigation with the potential intervention(s) and control(s) and measurable outcomes (Richardson et al., 1995; Sackett et al., 1995; Huang et al., 2006). This forms the PICO framework (Richardson et al., 1995), however for the purposes of systematic reviews the original PICO framework is extended to become Population, Intervention, Control, Outcome and Study Design (PICOS) to allow for the inclusion of study design methods for included citations within the review (Huang et al., 2006).

Table 3.1: Description of the PICOS criteria used to define the review question

Population	Individuals, aged 14-65 that meet the International Classification of Diseases (ICD-version 10) diagnostic criteria for psychotic disorder (WHO, 2016)
Intervention	Modification of diet or provision of diet supplements
Comparison	Placebo
Outcome	Symptoms of psychosis as measured by a validated psychosis rating scale
Study Design	Randomised Controlled Trials (RCTs)

Proctor and Hill (2013) stated that the design of a research strategy involves key decisions, which must start with understanding the key features of the target population. The development of the search strategy therefore started by defining what is meant by psychosis and then defining the intervention. The search facets were ‘psychosis’ and ‘Diet/Diet supplements’. These were developed as follows:

1) Psychosis: The subject of the review is ‘symptoms of psychosis’ and therefore the list of search terms was drafted using prior knowledge of this topic, which was extended and then ratified upon checking the ICD-10 diagnostic definitions of psychoses (World Health Organization, 2016).

2) Diet, diet supplements and nutrient supplements: The object of the review is ‘diet’ and ‘diet supplements’; the relevant search terms were initially drafted using prior knowledge of these subjects. The terms included diet, diet supplement, nutritional and food terms and any nutrient with a predetermined and recognised Reference Nutrient Intake (RNI). RNIs are determined internationally by the World Health Organization or nationally by the United Kingdom’s Department of Health, as ratified by the Scientific Advisory Committee on Nutrition (British Nutrition Foundation, 2021).

3.6.3 Development of Study Eligibility Criteria

Consideration was given to which study designs should be included within the review. The Cochrane Consumers and Communication Review Group (Prictor and Hill, 2013) give recommendations on which study design(s) to include based upon the inherent purpose of a specific research question. For this PhD, when answering a question on the ‘effectiveness’ of an intervention, only controlled trials were suitable for inclusion, and those where human participants are subject to randomisation are considered the gold standard (Prictor and Hill, 2013). Based on the characteristics of the target population, studies would be included irrespective of treatment location or duration of treatment. The reported outcome of included studies was an objective assessment of the variance in symptoms of psychosis (determined through a validated measure) post-intervention.

3.7 Development Phase – Step 2: ‘identifying/developing appropriate theory’ through exploring the views of stakeholders

Following the literature review, irrespective of whether an appropriate intervention exists or is still required, one of the next steps suggested by the MRC Guidance document for the development and evaluation of complex interventions (Skivington et al., 2021) is the need to seek the views of stakeholders on key aspects of the intervention. This is because it helps elucidate key elements of programme theory that will contextualise the needs of these stakeholders with respect to how the intervention is delivered (Skivington et al., 2021). One example of this is the potential format of the intervention. Key decisions were required and an outline of those and the corresponding theoretical underpinnings are outlined in the following sub-sections of this chapter:

a) Definition of stakeholders
b) Data collection strategies for each study
c) Data analysis method
d) Data synthesis to develop Programme Theory

3.7.1 Definition of 'Stakeholders'

For the purposes of clarity, the definition of the two stakeholder groups used in this PhD is important. Firstly, a Healthcare Professional (HCP) was defined as an individual contracted by the NHS Trust to provide a healthcare service to a patient who had experienced psychosis. The term Healthcare Professionals has been acronymised to HCP for ease of readership in later sections of this PhD thesis. The HCP cohort could comprise registered and non-registered professionals who are responsible for providing or supporting psychosis management interventions, such as nurses, psychiatrists, social workers, psychologists, and nursing assistants.

The definition of 'Patient' and 'Carer' are as follows – a patient is someone who has been in receipt of care and treatment for psychosis from an NHS service. The term patient is used in this thesis because it is the term of preference versus 'service user', cited in the published literature that represents individuals' views on this subject (Costa et al., 2019). A carer is someone identified as part of the 'care network' of a patient and who is not employed by the patient to provide care. Examples of individuals defined as carers include family members, spouses/partners or friends that offer support on a regular basis. This view concords with examples in the literature, which cite that the term 'carer' was originally a policy-driven term to place value on the contribution to care made by family members and friends as part of an individual's care network (Dirik et al., 2020). Patients and Carers were considered one stakeholder group firstly due to their shared experience of the receipt of psychosis services and because the carers may play a role in supporting patients with their dietary needs.

3.7.2 Data collection strategy for each study

There are a range of data collection methods that could be utilised to explore the views of stakeholders, such as surveys (quantitative methodology) and interviews (qualitative methodologies). Surveys have the advantages of being quick to administer and that the responses will arrive in a standardised format, however disadvantages include that the data provided are likely to lack depth and there's no opportunity to seek clarification or probe for depth on points of interest (Jones et al., 2013). Surveys can provide some limited context for an individual's experience of a phenomenon, such as the number of incidences of an experience, however they cannot give detailed information about the experience (Calnan, 2013). Interviews, on the other hand, are interactive and directly allow participants the opportunity to relay information and insights into what is important to them (Coleman, 2019).

According to the MRC Framework (Skivington et al., 2021), a diet intervention for psychosis management would meet the definition of a complex intervention and as such, its development would likely benefit from using a data collection method that allows a more interactive approach. To answer the research question central to this PhD, an interactive format which allowed participants to relay their views was required, and thus interviews were chosen to elicit the views of these stakeholders. There are different types and formats of interviews routinely used in the collection of qualitative healthcare data, such as structured and unstructured and group and individual (Broom and Willis, 2007). These formats are described in the next section and a justification given for the methods chosen for both the HCP and Patient and Carer data collection strategies.

3.7.3 Interview format

The structure of healthcare research interviews can range from highly structured, utilising a rigid set of pre-determined questions, to unstructured, which allows the conversation to lead the direction of the interview (Knox and Burkard, 2009). Structured interviews may restrict the data collected and reduce the ability to effectively capture the '*view'* or participants, whereas the data collected using unstructured interview techniques may not answer the research question, thereby making any comparison between subjects difficult (Knox and Burkard, 2009). An adaptation to interviewing is the semi-structured interview technique and Gray (4th Ed, 2018, pp381) stated that the semi-structured interview:

> *"allows for probing of views and opinions where it is desirable for respondents to expand on their answers"*

The semi-structured method comprises the advantages whereby sufficient freedom is given to the participant to help shape the conversation, whilst allowing the researcher to guide the data collection in such a way that it helps provide answers to the research question being studied (Adams, 2015). A semi-structured interview topic guide is developed with a minimal set of questions that relate to the core concepts of the research question (Adams, 2015). These are used in conjunction with the flexibility of a researcher to encourage further expansion on areas or specific points of interest (Adams, 2015). Furthermore, those that have experienced psychosis, may associate trauma with some of their past memories, which may be remembered during an interview (Druacker et al., 2009). Remembering some of these events from the past may lead to feelings of embarrassment, anxiety or stress (Jorm et al., 2007). For these reasons, the semi-structured interview format allows the participants sufficient freedom to speak, whilst allowing the researcher the flexibility to steer or support participants throughout the interview process.

The semi-structured interview design was chosen for use in the Patient and Carer study because of its flexible design. This was considered beneficial partly because the topic area of nutrition for psychosis isn't well researched, therefore negating the possibility to a develop pre-defined structured interview schedule. Furthermore, it was also unclear at the outset of this PhD, how much knowledge participants would have, so a semi-structured interview topic guide that could steer the interview was considered helpful (Kallio et al., 2016).

3.7.4 Interview setting

Another key component to successful data collection through interviewing is consideration of where the interview will be conducted: in person or remotely. In-person interviews are usually conducted face-to-face, which can present logistical drawbacks and increase the resource requirement (Adams, 2015). The use of assistive technology for conducting focus groups has been the topic of debate for decades (Underhill and Olmsted, 2003; Abrams et al., 2015), with benefits noted, particularly for vulnerable individuals and hard to reach groups, including those with severe illnesses (Tates et al., 2009; Nicholas et al., 2010; Rupert et al., 2017). The face-to-face approach was traditionally considered to result in higher quality data as opposed to data collected via remote methods, such as by telephone (Sturges and Hanrahan, 2004). More recent evidence, following the Covid-19 pandemic, suggests no practical issues were encountered nor was data quality adversely affected using remote interviewing for the majority of participants, however some groups were not keen (Keen et al., 2022, suggesting that individuals ideally should be offered a choice.

The empirical qualitative investigations within this PhD, are aligned with a Pragmatist view where greater value would be gained through offering participants flexibility in the choice of interview location, which aligns to Pragmatism's values-bound axiology. Examples include the choice between face-to-face or remote and between conducting interviews within NHS buildings and within patients' or carers' homes. The decision to include patient or carers' homes was taken to be reflective of current NHS service delivery and was supported through local policies, procedures and risk assessments within the host NHS Trust (See Practical Methods, Chapter 5, Section 5.7). Ensuring improved access to participation may link to the ontology through data being derived from a freer, more honest and open dialogue within their interview sessions. This is an important quality marker for interview data (Rupert et al., 2017) because it is viewed as being more representative of the experiences and thus contributing to knowledge set within the context upon which the phenomenon is based.

3.7.5 Individual versus group participation

Interviews with one researcher and one participant have the advantage that they can extract very detailed data from one individual and the flow of the questions can be directed by the individual's needs (Rowley, 2012). Likewise, the researcher has a greater opportunity to expand on point with the individual participant and go back to seek clarity to improve the meaning (Rowley, 2012). This is a further advantage for those with psychosis who may struggle with social functioning and would be intimidated by group participation can gain trust in an individual interview setting (Rowley, 2012).

In healthcare research, whilst there can be merit in conducting interviews between a single researcher (interviewer) and a single participant (interviewee), there can also be value in conducting interviews with a group of participants where group participants have shared experiences or characteristics related to the research question (Kitzinger, 1995). Group discussion is particularly beneficial in instances where questions are open-ended and participants' views on a given topic are sought (Kitzinger, 1995).

There was the potential to use group interviews for patients and carers simultaneously, which benefit some individuals, such as those who require longer to process information (Morgan et al., 2013), it was considered by the researcher, that this may curtail some of the ability of both parties to speak freely on their experiences (Zarhin, 2018). It may also inhibit participants from being completely open and honest in relation to expressing their views with another member of their care network (Zarhin, 2018). Likewise, the use of a dyadic approach, could however limit data collection by excluding participants who could not find a suitable dyad. This methodological approach would generate a dataset of limited value and thus would not therefore fit with the pragmatist approach underpinning this PhD.

3.7.6 Focus Groups

A different type of group interview technique, called a 'Focus Group', collects data, such as opinion, experience, anecdotes and views of the individual participants and data generated through the combined interaction between participants and between participants and the interviewer that leads to valuable data on a given topic (Coenen et al., 2012). In addition to the value from the combined influence of different experiences of a phenomenon, the focus group method has the added advantages of collecting data from participants that may be reluctant to be interviewed on their own and from participants who feel they would have nothing to say (Kitzinger, 1995).

Acocella (2012) claims that whilst the focus group has undoubtedly become a very popular technique, this may partly be due to its relatively inexpensive and quick nature as a method of extracting data from several participants at once. The nature of a focus group though is not to seek several individual accounts at one time, it is to elicit a richer view on a topic through active group participation (Kitzinger, 1995). The focus group approach was used within this PhD to seek the views of the healthcare professionals (HCPs). The rationale for choosing this technique for this stakeholder group is that by the nature and essence of group discussion centred on shared experience, individuals may be triggered via conversation with peers to remember additional experiences (Nyumba et al., 2018). Likewise, the researcher can note the impact of the views of others, which can add further meaning to the data (Nyumba et al., 2018). Examples include the impact of someone challenging a particular view expressed by someone in the group, which may then lead to either a richer defence of their viewpoint or a change of opinion. The focus group therefore can provide additional contextual factors related to the phenomenon, as compared with the views of sole participants interviewed individually.

3.7.7 Summary of interview techniques used in this study

As previously outlined, collecting data from HCPs would be best completed in a group setting where the range of experiences can help construct meaning to the phenomenon being studied, therefore focus group sessions were chosen for the HCP stakeholders. The experiences of patients and carers would be individual, however, and therefore an individual semi-structured interview was considered the most appropriate format for data collection from the patient and carer stakeholders. The decision was taken because from an axiological point of view, it would avoid the potential risk to participants feeling anxious, embarrassed or stressed following any recall to acute phases of their illness (Jorm et al., 2007) whilst in a group setting, such as a dyadic interview.

The use of the interview methods chosen: individual semi-structured interviews (patients and carers) and a series of focus group interviews (HCPs), would elucidate the participants' views on topics including their knowledge and perception of whether diet has a role to play in brain health and whether they consider diet an acceptable and useful intervention for the management of psychosis.

3.8 Sampling strategy

There are a range of sampling strategies that can be employed when conducting qualitative research, with the most common being "purposeful sampling" (Creswell, 1998). A purposeful sampling strategy allows the researcher(s) to identify sites, cases and events that are likely to inform the inquiry and provide data that answers the research question (Creswell, 1998). For the purposes of this PhD, a purposive sampling strategy was chosen with the sites and cases approached and recruited to this study having prior experience of psychosis.

3.8.1 Sample size justification and when to stop collecting data

Quantitatively orientated studies determine sample size through a power calculation, which considers attributes such as the minimum number of participants required to determine a particular effect size, the expected rate of attrition and the sensitivity of the statistical test(s) being applied to the data. Qualitative studies have no such standards of assessment (Marshall et al., 2013). Glaser and Strauss (1967) developed the term ‘data saturation’ to signify the point in the data collection process where adding new data would bring nothing new to the analysis and resultant findings. It is noteworthy that Glaser and Strauss (1967) were conducting a study using the principles of Grounded Theory, whereby the researcher is continually evaluating and analysing concurrently and thus a finite sample size could not be decided upon in advance of the analysis process. A more recent term: ‘theoretical saturation’ is described as the point whereby the inherent properties of categories and the relationship between categories are explained sufficiently to provide a theory (Morse, 2015). This too is therefore aligned to a grounded theory approach. Nelson (2017) suggested the term: ‘conceptual density’ to allude to the point whereby the data provides sufficient ‘depth’ and ‘richness’ to move away from the term ‘saturation’. Low (2019) believed that ‘data saturation’ has been interpreted by many qualitative researchers to mean information redundancy, upon which basis these researchers defended their sample size and have justified ending study recruitment and data collection.

Braun and Clarke (2019) have theorised on whether data saturation is useful to consider when conducting thematic analysis. They suggest that the need to quantify or demonstrate provability within a study’s sample size relates to the neo-positivist approach, which they consider is a tool used by many to justify a study’s actual or pragmatically determined sample (Braun and Clarke, 2019). Whilst they reject the concept of data saturation as being valuable for a reflective thematic analysis approach, they do consider that some key factors should be considered when deciding on when to stop recruiting data subjects (Braun and Clarke, 2019). These key factors include attaining a measure of experiential and identity-based diversity within the data, the depth of data generated from each participant, the demands placed on the participants and the pragmatic constraints of the project (Braun and Clarke, 2019).

Braun and Clarke (2021) contend that meaning is generated from the data as part of reflective thematic analysis and therefore assumptions about the content or quality of data prior to data collection are potentially flawed. For that reason, they consider that the decision to know when to stop recruiting should be flexible enough to be determined as part of the data analysis.

The basis of data sufficiency for this PhD balanced findings within the wider literature on this topic, with the needs of a Pragmatic inquiry, which required clearly defined parameters to be cited in a protocol ahead in order to seek ethical approvals for the two studies. One example of a study that sought to objectively justify their sample size was Guest et al. (2006), who used a codebook they had developed following conduct of a phenomenological study with individual interviews of 60 participants. They cited that of the 109 codes, 73% were identified in the first 6 interviews, with 92% identified in the subsequent 6 interviews and 100% were attained following completion of the 13th interview (Guest et al., 2006). They applied a statistical test: Cronbach's Alpha to measure the reliability of code frequency, which sets an acceptable range at between 0.70 and 0.90 and found that 0.70 was attained after 12 interviews (Guest et al., 2006). In terms of group interview justification, the findings of a further study by Guest et al. (2017) using group interview studies were considered. They suggested that at two focus groups are required to generate at least 80% of themes on a particular topic and that 90% of themes were discovered through data collected from three to six focus groups (Guest et al., 2017). Likewise, Thomson (2010) conducted a review of 50 qualitative studies with respect to their sample size determination and concluded that data saturation generally occurs between 10 and 30 interviews and that a key part of saturation is to conduct a set number of further interviews, e.g. two additional interviews to ensure that data saturation has indeed occurred. A description of how this was conducted in practice is given in the practical methods chapter (see Chapter 5, Section 5.15).

3.9 Patient and Public review of study materials

It is important to the success of research studies that the research plan and associated study materials should be appropriate for the potential participants (Hoddinott et al., 2018). The materials, including the consent form and information sheets must contain sufficient information to allow the participant to understand the aim of the study, and understand what is being asked of them if they participate (Hoddinott et al., 2018). For the purposes of this PhD, the views of individual patients, carers and HCPs were sought on the key documents within the respective studies, prior to finalisation and prior to submission for regulatory or ethical approval.

3.10 Ethical considerations

Ethical review of health-related studies involving human subjects remains important to ensure that all individuals are treated fairly and in accordance with standards developed from the Nuremberg Code (Code, 1949) and the Declaration of Helsinki (World Medical Association, 2013). The Nuremberg Code was drafted in August 1947 detailing a set of standards that whilst never ratified, underpin modern standards for the conduct of care and research involving humans: The Nuremberg Code, 1949). A summary of the key aspects of the Code indicate that the research should be conducted using appropriate facilities, equipment and personnel that are suitably trained, that the benefits of conducting the research should outweigh any disadvantages and should be without any undue suffering, should fundamentally be underpinned by a clear rationale for its conduct and conducted with the caveat that the study can be stopped at any point if there are safety issues and that any participant has the right to withdraw at any point, without any detrimental impact to them (Fischer, 2006). The Research Governance Framework for Health and Social Care (Department of Health, 2005b) sets out the standard of the ethical conduct of research involving human subjects, conducted in England. Conduct of research studies within the NHS is monitored through the ratification of study protocols and procedures through review by the Health Research Authority (HRA) and independent national research ethics committees (NREC) (Health Research Authority, 2023a). The approvals process ensures that all studies are reviewed by independent panels and all queries or suggested amendments must be resolved prior to approval being granted (Department of Health, 2005b).

3.11 Data analysis method

Miles and Huberman (1994) contended that the methods used to analyse qualitative data are not homogenised and are custom-built to fit the nature of the study in question. The process of data analysis is the most complex aspect of qualitative research yet has often had the least explanation in the published literature (Nowell et al., 2017). The important outcome of data analysis, particularly from the Pragmatist position of this PhD, is to ensure that a systematic method of data analysis is used that can be transparently communicated as part of the final report (Malterud, 2001).

3.11.1 Recognised methods

Creswell (1998) cited ‘5 traditions’ when referring to qualitative data analysis methods, which were phenomenology, grounded theory, biography, case study and ethnography. Over the last two decades, another method called thematic analysis has gained both popularity and credibility as a distinct analytical method for qualitative studies in healthcare (Braun and Clarke, 2012). The key features of each of these methods are presented in Table 3.2.

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Table 3.2: Overview of qualitative data analysis methods

Method	Key Feature(s)	Source
Biography	• Focussed on the individual (participant) and related to their key life events (e.g. Marriage or career points) • Narrative developed by the researcher through applying meaning/searching for patterns in selected segments of the participant's life-story	Creswell (1998)
Phenomenology	• Focussed on the participant's experience of a phenomenon or event of interest • Interpretation of excerpts from the data by researcher(s) conducted in order to capture the 'essence' of the experience	
Case Study	• Focussed on the detailed description of individual cases, including the setting or context associated with those cases • Collections of instances from the data are interpreted by the researcher for meaning and to establish potential patterns that the researcher perceives exist	
Ethnography	• Highly in-depth description of the setting or context related to the study participants • Use of tables to present comparable features and support comparison to other groups	
Grounded Theory	• Provides a framework for developing and connecting categories and thus building a story • One of the categories is identified by the researcher as a central phenomenon and the other categories are then appraised in terms of relationships to the central category	
Thematic Analysis	• Highlights common features from across the data that allows the researcher to find and discuss meaning	Braun and Clarke (2012)

From a pragmatic philosophical position, the value of each of these recognised methods must be appraised in relation to their potential to answer the research question. The data collected from stakeholders related to views and experiences of diet intervention for psychosis management. As the systematic review indicated there were relatively few examples of diet interventions trialled for psychosis management, therefore methods such as case study, ethnography and biography were not considered suitable due to their inherent approach relying upon gathering in-depth accounts from one or two individuals with significant experience of the phenomenon (Creswell, 1998). Phenomenology was also discounted due to an investigation of the essence of the experience being of limited practical value in the development of a diet intervention where the participants level of knowledge of the phenomenon is yet unknown. A grounded theory approach to data analysis was considered to have more merit, however the focus on a single category being considered the central phenomenon (Creswell, 1998) did not fit closely with the aims of this study. Likewise, data analysis leading to a detailed, or 'thick' description of what happens within a phenomenon (Ponterotto, 2006) would not be appropriate as it is unclear whether participants within this PhD's studies would have sufficient knowledge of the topic.

Thematic analysis, particularly the 6-stage method outlined by Braun and Clarke (2006), held the advantages that it is a robust, yet flexible method of qualitative data analysis (Nowell et al., 2017) that supports the researcher to make sense of a collective set of experiences through highlighting common features in which an experience is written or talked about by a group of individuals (Braun and Clarke, 2012). Thematic analysis also had the advantage that the researcher conducting this PhD could utilise their own prior professional knowledge and expertise of diet and psychosis to construct meaning from the data. The use of thematic analysis as method also accords to the MRC Framework's intervention development phase, whereby researchers should construct meaning from the views of stakeholders to guide the development of a proposed intervention (Skivington et al., 2021).

It must be acknowledged that Thematic Analysis is a term that has been previously misused and has been associated with studies published with a poor description of their data analysis strategy (Braun and Clarke, 2006). Braun and Clarke's response to this was to publish their 6-step guide to thematic analysis (2006), which provided a systematised approach that supported a robust and potentially transparent method of analysis. One of their aims was that the production of this guide would help improve the quality of qualitative data analysis and reporting in the field of psychological and other health-related research (Braun and Clarke, 2006). One of the decisions they recommend should be taken prior to commencing data analysis is whether to take an inductive or deductive approach to the analysis, as this will guide the next steps (Braun and Clarke, 2006). An 'inductive' approach was taken to generate a theory based on the data collected as part of this PhD, rather than deductively applying a pre-existing framework to the data. Braun and Clarke's (2006) method clearly outlined a systematised, inductive approach to thematic analysis and that was the principal reason that it was chosen as the data analysis strategy for this PhD. It was a robust and well-cited method of thematic analysis, but the clarity the 6-step approach afforded was beneficial to a researcher that was relatively inexperienced at qualitative data analysis (Braun and Clarke, 2006).

3.11.2 Ascertaining the value of the data collected throughout this PhD

The more objectivist part of this PhD, the Systematic review and meta-analyses of previously conducted trials was subject to scrutiny, not only through the use of standardised statistical measures, but also the application of the 2009 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher et al., 2009). The use of these appropriate standardised tests help understand the ‘trustworthiness’ of the reported outcomes and thus whether they have validity, reliability and objectivity, which are important measures of rigour and the quality of quantitative research findings (Heale and Twycross, 2015). The more subjectivist parts of this PhD, however must also be trustworthy, but the concepts of validity, reliability and objectivity are rendered invalid due to the fundamental differences in what constitutes reality and knowledge (Curtin and Fossey, 2007). These are replaced with the following terms: credibility, transferability, dependability and confirmability (Korstjens and Moser, 2018). Credibility relates to the confidence that can be placed in the truth of the research findings, whilst transferability relates to whether a set of findings would continue to have meaning in other contexts (Lincoln and Guba, 1985). The dependability criterion considers the stability of the findings over time and then confirmability explores the degree to which the findings presented could have been found by other researchers (Lincoln and Guba, 1985).

As part of the defence of this PhD, consideration was given to the fact that whilst Braun and Clarke’s 6-step method was clear in terms of the analysis process, not all of the methodological steps were fully furnished with practical suggestions, such as suggestions for data handling. These features are important to provide assurance to the reader of the quality and ‘trustworthiness’ of the data. Nowell et al. (2017) outlined a practical procedure that aimed to demonstrate and evidence adherence to the key trustworthiness criteria described by Lincoln and Guba (1985) utilising the 6-step method outlined by Braun and Clarke (2006). At each of the 6 steps of the analysis process, Nowell et al (2017) described key practical processes aligned to each step to demonstrate assurance to the reader the detail and assiduity with which the research had been conducted. Examples of these steps include reflexive journaling of the process, development of an audit trail of code generation and the development and use of a file management system to ensure that data was systematically stored and appraised (Nowell et al., 2017). These are described within the thesis text (including excerpts from the reflective journal) and as appendices (examples include Appendices 16 and 17: the audit trail for code generation and the development of themes).

3.12 Data synthesis to develop Diet Intervention Programme Theory

It was acknowledged earlier in this chapter, the inherent value in considering the two stakeholder groups separately for ontological reasons, was that their perceptions of the phenomenon and perceptions of reality would be distinctly different. HCPs' experience of psychosis is from the point of providing care, whilst patients and carers' experiences are from a receipt of care perspective. To that end the two datasets were treated separately, collected using different qualitative methods for data collection, but were analysed using the same method of thematic analysis (Braun and Clarke, 2006).

One of the strengths of Pragmatism is that any inquiry rooted in Pragmatism views the same phenomenon from different perspectives. Pragmatists believe therefore that in order to determine 'what works' it is logical to find meaning from the combination or synthesis of differing datasets (Maarouf, 2019). This tallies with the theoretical perspective of the MRC Guidance, which cites that the views of all relevant stakeholders are important to determine the context and systems within which an intervention will operate (Skivington et al., 2021), thus avoiding the loss of marginalised voices, such as patients and carers. Denzin and Lincoln (1994) consider that triangulation of data collected from two different sources provides a more in-depth understanding of the phenomenon under investigation. Within this PhD findings from both of the qualitative studies exploring the views of stakeholders (HCP and Patient and Carer groups) will firstly be reported and discussed individually and then will be synthesised to elucidate 'what works' in the form of the core elements of a diet intervention for psychosis management.

3.12.1 Triangulation and synthesis of the data

Data triangulation aims to provide an output where the sum is greater than the addition of the two individual parts (Barbour, 1999). Farmer and colleagues (2006) developed the triangulation protocol, which outlines six key steps the authors believed were required to systematically enact triangulation of findings from two qualitative studies and estimate completeness of data and areas of convergence or dissonance. One of their key outcomes, linked to the 6-step approach was to ascertain the frequency of themes provided and another was the development of a convergence coding matrix (Farmer et al., 2006). The convergence coding matrix supports the development of meta-themes (Farmer et al., 2006), which span the individual studies and facilitates the comparison of findings from the different studies to note areas of agreement, dissonance and silence (O'Cathain et al., 2010).

3.12.2 Programme theory

The aim of this PhD inquiry was to ascertain the value of providing a complex healthcare (diet) intervention for psychosis management. The outcome, therefore, of triangulating the findings from this PhD's two qualitative studies should be to advance the programme theory development of a diet-related support intervention for psychosis. Programme Theory describes the ways in which components of an intervention or programme contribute to a chain of actions that lead to impact, which may be intended or unintended and may be beneficial or negative (Rogers, 2008). One of the aims of programme theory is to develop a causal model, which can be used to guide evaluation of the intervention (Rogers, 2008). Programme theory is a key element suggested within the MRC Guidance for the development of a complex healthcare intervention (Skivington et al., 2021), Programme theory has been subjected to criticism in that whilst it is the overarching theory explaining how an intervention should work, however a historical lack of clarity on how researchers should operationalise has been noted (Maden et al., 2017). With evidence that is has been used in a fragmented and non-systematic way (Maden et al., 2017). The importance of programme theory is clear as a central component of the development of a diet intervention and its use is justified within the MRC Framework for complex intervention development (Skivington et al., 2021). It was important, however to ensure that its use was applied in a systematic way (Maden et al., 2017). The use of logic models can support the systematised use of programme theory, through showing the relationship between the elements of the programme (intervention) and how, when combined these produce optimal outcomes (Funnell and Rogers, 2011).

3.12.3 Logic Models presented in this PhD: an overview

Logic models are designed to consider the interventional outputs, outcomes, and onward impact as determined by activities and the input of resources (Funnell and Rogers, 2011). There are four main types of logic model: pipeline, outcome chains, realist matrices and narratives (Funnell and Rogers, 2011). Of these types, the Pipeline model was best suited to illustrate the programme theory in answer to the research question in this PhD. This is because at this early stage within the development phase of a complex intervention such as diet intervention for psychosis management, it is key to build knowledge on required resources (example: personnel, materials) and activities or processes (example: designing dietary feedback documents) that will lead to outcomes (example: improved knowledge on diet for psychosis) and potential areas of impact (example: improvement in psychosis) (Funnell and Rogers, 2011). In addition to considering these key components articulated within a logic model, there are another two important additions to programme theory: assumptions (Kaplan and Garrett, 2005) (example: that service providers are keen to deliver new interventions for psychosis management) and external factors (Greenfield et al., 2016) (example: a pandemic). It is crucial to outline the assumptions related to the development of a new intervention, which some contend is the most critical element because it helps elucidate the gaps in the existing programme theory (Kaplan and Garrett, 2005). Likewise, the external factors, which include changes in economic circumstances or the development of a new policy, will also impact on the development and subsequent delivery of an intervention (Greenfield et al., 2016).

The advantage of using a Logic Model to represent the core components of a diet intervention for psychosis management is the clear articulation of both the known and unknown areas of programme theory generated through the synthesised findings. An example of this includes convergent data suggesting that diet supplements should be prescribed to those with psychosis who were found to be deficient for key nutrients, but no data was elicited around the resource requirement, such as a source of funding or the need for medical or non-medical prescribers (see Figure 12). Following the integration of the two studies' findings, it was apparent that the synthesised data provided key elements of programme theory and contextual factors required for the development and delivery of a diet intervention for psychosis management. These included the need for a change of attitudes of HCPs responsible for providing care within NHS organisations and the need to develop a knowledge-based intervention. Both programme theory and context are core components of complex interventions aligned to the MRC Guidance (Skivington et al., 2021), as is the conduct of studies such as those synthesised here, as this represents the engagement of stakeholders.

The presentation of intersected or triangulated data in a logic model clearly aligns with Pragmatism in that there is clear practical value realised from presenting the intersected data in a way directly supports the development of a diet-related intervention for psychosis management. Furthermore, a narrative on the outcomes of the triangulation process whereby the important areas of convergence, silence or dissonance (Farmer et al., 2006) adds value to understanding what contribution this PhD will make to the development of the intervention and what areas require further discussion. This allows for a clear understanding of the implications of this research to be drawn out and presented and a clear understanding of the next steps required following this PhD. To that end, the production of theoretical meta-themes from synthesised datasets, as suggested by Farmer et al. (2006), would not answer the research question at the centre of this PhD. The decision was taken therefore to follow the Triangulation protocol as developed by Farmer et al. (2006), but not to produce a series of meta-themes, but instead to synthesise and present the findings into a pipeline logic model (Funnell and Rogers, 2011). A clear description of the key stages of the triangulation protocol in relation to the conduct of this PhD is listed in Table 5.4, presented in the Practical Methods Chapter of this PhD (See Chapter 5, Section 5.19).

3.13 Chapter Summary

This chapter has described the theoretical considerations relevant to this PhD which used a Pragmatic mixed-methods approach to explore whether there is value in providing diet intervention for psychosis management. This chapter articulates the rationale for the Pragmatic philosophical underpinnings of this PhD, alongside its alignment to the MRC's theoretical framework for the development and evaluation of complex healthcare interventions (Skivington et al., 2021). Within the chapter detail is given on the application of the explanatory sequential model (Creswell and Plano-Clark, 2017) for the conduct of this PhD and it articulates the theoretical discussion throughout the conduct of this PhD. For the purposes of this PhD, a combined approach was taken to support theory testing when reviewing and meta-analysing existing published trials (explanatory) with theory generation to explore pertinent contextual factors when consider the development of a diet intervention for psychosis management (exploratory).

The chapter also summarises the theoretical underpinnings of key decisions and processes related to the conduct of the PhD, such as the need for sound ethical decisions and a discussion and rationale on the research methods chosen. An example includes the theoretical basis for considering group versus individual interview data collection strategies for respective stakeholder groups. The latter part of the chapter explores the value of triangulation to synthesise findings and then the components of programme theory and their relevance to this PhD inquiry.

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4. REVIEW OF THE LITERATURE

This chapter describes the reporting of a systematic review of peer-reviewed published Randomised Controlled Trials (RCTs) that tested the efficacy of diet interventions for the management of psychosis, which was undertaken to inform the research question (See Chapter 1, Section 1.1) and the subsequent phases of this thesis. This review was conducted in line with the process recommended at the time of conduct, which was developed by the Cochrane Collaboration (Higgins and Green, 2011) and supported by the recommendations of the MRC when developing or evaluating complex healthcare interventions (Skivington et al., 2021), as described in Chapter 3, Section 3.5. The chapter is presented in line with the PRISMA statement (Moher et al., 2009), which provides a sequentially ordered checklist of the items for reporting of systematic reviews and meta-analyses. Detailed descriptions are added throughout this chapter, including an explanation of additional calculations required to support the meta-analyses conducted (n=2), where appropriate. The practical methods employed as part of the conduct of this systematic review are described within this chapter, which include the processes of citation selection and data extraction for included studies. The results section of this chapter includes metrics detailing database searches and citation screening metrics, followed by a description of the characteristics of the studies included in the review. Within this chapter the researcher has provided excerpts from their reflective diary in places where their inclusion would add value (Davis, 2020) to the chapter, such as through describing the rationale for a particular thought process, or decision. The chapter commences with the systematic review question, aims and objectives.

4.1 Defining the review question, aims and objectives

4.1.1 Review question

The aim of this PhD is to explore the value of diet intervention for psychosis management and thus the review question was developed in line with the explanatory sequential design of this PhD to ascertain what diet or diet supplements have been trialled for efficacy at managing psychosis symptoms. The question was formulated using the PICOS criteria, as described in Chapter 3, Section 3.6.2 (Table 3.1):

To what extent have diet or diet supplement interventions been trialled for efficacy versus placebo for the effective management of psychosis symptoms in individuals aged 14 - 65?

4.1.2 Review aim

To review the extent that diet or diet supplements have been trialled for their efficacy at managing psychosis symptoms.

4.1.3 Review objectives

i) To extract data from RCTs investigating the efficacy of diet on the symptoms of psychosis;

ii) To extract data from RCTs investigating the efficacy of diet supplements on the symptoms of psychosis;

iii) To report descriptive statistics on RCTs investigating the efficacy of diet or dietary supplement interventions on the symptoms of psychosis;

iv) To meta-analyse data, where appropriate, from RCTs investigating the efficacy of diet or nutrient(s) interventions on the symptoms of psychosis;

v) To report and discuss the findings of the systematic review, and meta-analyses (where appropriate)

4.2 Protocol and Registration

This systematic review and meta-analyses are reported using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher et al., 2009). The review was registered with The International Prospective Register of Systematic Reviews (PROSPERO), CRD42018091310, accessible from: https://www.crd.york.ac.uk/PROSPERO .

4.3 Defining the search strategy

4.3.1 Inclusion and Exclusion criteria

Prior to a full search for the systematic review, the development of study inclusion and exclusion criteria were required in order to ensure a consistent approach in line with systematic review methodology. The inclusion and exclusion criteria are shown in Table 4.1 and were developed and refined as an iterative process through a variety of resources, including the Cochrane Handbook for systematic reviews version 5.1 (Higgins and Green, 2011), advice from two NHS Librarians and through discussion with the supervisory team.

Trials published in languages other than English were excluded due to the inability to understand the original text and the lack of assurance in the accuracy of a translated copy. The exclusion of non-English language publications has been found to have no effect on the conclusions of systematic reviews (Nussbaumer-Streit et al., 2020). Trials using animal subjects were also excluded because outcomes in animals may not translate adequately to outcomes in humans. Also, there are physiological differences within humans and between adults, older adults and children, all of which may impact on their nutritional requirements (Department of Health, 1991). In physiological terms, a child’s nutritional requirements for key nutrients, such as fatty acids, would equate to those of an adult once they have reached puberty (Department of Health, 1991). To align therefore with this physiological demarcation, the definition of ‘adults’ for participants within included studies as part of this review, was defined as participants aged 14-65. The lower age range of 14 was used, as opposed to 16, to parallel the inclusion range for adult community services in England, which is 14-65 (NHS England, 2023)

One of the key features of a systematic review is a timeframe in which the studies were published. For the purposes of this inquiry, a guideline, published in 2005 was one of the first guidance documents worldwide to recommend consideration of nutrition as part of psychosis treatment to psychiatrists and mental health (Department of Health, 2005a). This date was therefore chosen as the timepoint for the inclusion of studies trialling diet-related interventions to manage psychosis that would be relevant in the context of current service provision. Trials published prior to the publication date (2005) of this Guidance document were also excluded.

Table 4.1: Systematic review inclusion and exclusion criteria

Inclusion Criteria	**Exclusion Criteria**
1) RCTs of diet or diet supplement where the primary outcome is the effect of trial agents on existing psychotic symptoms in adults being treated for psychosis	1) Studies other than RCTs 2) Trials that consider the effect of nutrient(s)/diet on the physical health of those with active symptoms of psychosis 3) Trials that consider the action of nutrients, which have not been consumed orally by study participants, e.g. those that are synthesised in vivo
2) RCTs involving human subjects in any healthcare setting	4) RCTs involving animal subjects
3) RCTs published in peer-reviewed journals	5) RCTs published in oral or poster presentation format only
4) RCTs with subjects aged 14 - 65 years (inclusive)	6) RCTs with subjects under the age of 14, or older than 65 at the time of participation
6) RCTs published between 2005 and 2019*	7) RCTs published before 2005
7) RCTs available in English language only	8) RCTs published in a language other than English

**The review was updated in 2023 prior to submission of this thesis and a discussion of the potential impact of subsequent studies is included at the end of this chapter, see Section 4.19.*

4.3.2 Information sources

Databases used to search for literature were accessed through the Healthcare Database Advanced Search (HDAS) interface located in the online NHS Evidence portal. This database allows for the application of search 'limiters' at the outset, such as limiting the search of published citations by study design, such as restricting to RCT methodological design and excluding systematic reviews. The databases Medline, AMED, CINAHL, BNI, PsychInfo, HMIC, HBE and Embase were chosen for this systematic review, as these are a repository for the publications from the field of medicine, mental health, nursing, psychology and the allied health professions. The choice of these databases was made initially because these are well recognised for use in healthcare-related systematic reviews and secondly these were discussed as part of the PhD supervision process and a joint decision was made that these were sufficient for a robust systematic review. The search of the Medline database was carried out on 9th and10th May 2017 and the remaining databases were searched on 21st June 2017.

4.4 Database Search

Specialist advice was sought from NHS librarians on the topics of search terminology prior to conducting the search, such as the use of Medical Subject Headings (MeSH) and the knowledge required to use the truncations and wildcards within and adapt their usage between specific databases. MeSH is an internationally used classification system that allows familial hierarchy to aid indexing and cross-referencing of related articles (National Library of Medicine, 2022). It is important to ensure that both text word and MeSH searching are conducted because there is a delay of up to six months between the inputting of articles referenced only by text word searching and the indexing and classification of articles into corresponding MeSH terms (National Library of Medicine, 2022).

Each search term was inputted individually into the search function as individual search rows, firstly as text words and then as phrases, checking for truncated words and wildcards (see Appendix 1). A search was also made to locate adjacent words that may be next to (ADJ) or a few words apart from the keyword (e.g. ADJ3) in the search box. The words were then checked using the HDAS thesaurus to find the Medical Subject Headings (National Library of Medicine, 2022). These measures were done to improve the efficiency of searching within databases and to reduce the potential for missed citations. An additional quality assurance check applied to the first search, which was conducted using the database Medline. This database was picked as the first one to be searched primarily due to its large volume of citations relative to the other databases. This initial search allowed a test of the accuracy of the search terms at sourcing appropriate citations, and to give an overview of the methodologies utilised in the published literature. The assurance check employed was that a proportion of these initial citations (first 50 citations) were extracted from the search and were discussed with the supervisory team to determine whether the search terms were returning appropriate results and whether there appeared to be sufficient RCTs conducted to warrant a full systematic review. As part of the discussion, a check was made whether the sub-section of results contained studies that related to the inclusion and exclusion criteria. As there were three studies that warranted abstract screening, the search terms were considered appropriate to proceed to the main search.

Search limitations were applied to restrict the citations to English language RCTs with a date limit post-1st January 2005 (inclusive). This date is important as it aligns with the timing of key policy documents suggesting improvements to mental health services, including diet intervention (Department of Health, 2005a; discussed in the Background Chapter: Chapter 2, Section 2.14). The latter publication is one of the first published guidelines worldwide to cite diet and nutrition as important for people experiencing psychosis (Department of Health, 2005a). This date was chosen as a logical timepoint where the ‘treatment as usual’ aspect of care would bear sufficient relevance to current treatment as to provide a valid comparator. The search across all databases was first conducted on 21st June 2017, with an updated search conducted on 9th July 2019.

4.5 Hand searching the bibliography of included articles

In addition to searching the indexed databases for potential RCTs, hand searching of the bibliography of included studies was also meritorious as a potential source of additional studies that may have been missed from the indexing process (Craane et al., 2012). This was conducted by the researcher and led to no additional studies for inclusion.

4.6 Search Timeline

The totality of this systematic review, including database search and citation extraction and review, meta-analysis and the production of findings was conducted over a period of two years. Prior to the finalisation of the findings of the systematic review, which would then inform the subsequent phases of this PhD, it was prudent to conduct an updated literature search, using the same processes as used in June 2017. This search was conducted on 9th July 2019 to check for any recent citations that warranted data extraction and inclusion in the review. The results of this were incorporated into the systematic review's results and discussion and helped inform the subsequent studies conducted as part of this PhD.

4.7 Study Screening and Selection

Following conduct of the search across all databases, the pooled citations were all imported into Covidence (Veritas Health Innovation, Melbourne, Australia), a software programme which facilitates citation screening. All titles from the main search were screened based upon their title against the study inclusion criteria (see Appendix 2) by the Lead Researcher between June 2017 and May 2018 for the initial search and then in July 2019 for the updated search. Citations that warranted further screening based on titular review were highlighted and these were then screened based upon review of their abstract. A proportion of those abstracts from the main search (2017), starting with the first paper and then every 20th successive paper (n=24), were screened by a second reviewer (secondary PhD supervisor). All citations that were queried (n=6) following this process, was resolved through discussion within the supervisory team.

4.8 Data collection process

An a priori data extraction form based on the Consolidated Standards of Reporting Trials (CONSORT) Statement (2010) (Schultz et al., 2010) was devised by the Lead Researcher using Microsoft excel (See Appendix 3, which details an excerpt). The data extraction document was a single repository for all data items collected for each study and contained sections to facilitate the application of the Risk of Bias tool (Higgins et al., 2011). This form was piloted using two studies and then reviewed and refined following discussion with the supervisory team.

4.9 Data items

Data collected pertained to the primary outcome by which the efficacy of trial agents was measured was mean variance in the total symptoms of psychosis, as determined by a validated psychosis rating scale, when compared to placebo or standard treatment. A beneficial effect therefore equated to a statistically significant mean improvement (reduction) in total symptoms of psychosis from the treatment arm, relative to the placebo arm, as indicated by a validated psychosis rating scale. A secondary outcome of the review was to consider whether there was statistically significant mean improvement (reduction) in any of the sub-scales of psychosis from the treatment arm, relative to the placebo arm, as indicated by a validated psychosis rating scale.

Data pertaining to the sample characteristics, including age, diagnosis and sample setting were also extracted from the studies. Descriptive data detailing the characteristics of interventional agents and placebos, including format of trial agent (e.g. foodstuff or capsule) and concentration/dosage (if appropriate) was also collected, as was descriptive data describing whether the treatment was standalone or adjunctive. Finally, data that supported the validity of the results, including whether diet recording or biochemical indices were reported and attrition rates were also extracted.

4.10 Assessment of internal and external validity

Both internal validity (quality of the methods used in the review and the quality of the conduct of the studies included in the review) and the external validity (how generalisable the results of the review are) represent the credibility or trustworthiness of a systematic review and meta-analysis (Avellar et al., 2017). The measure of internal validity relates to the potential for bias to exist (Avellar et al., 2017) and is measured using a series of validated outcome measures (see Section 4.10.1, below). External validity relates to a commentary and narrative appraisal of key study features, such as sufficient samples within studies to detect the desired effect from the trialled agent; homogeneity or diversity in participant characteristics like diagnosis, age, study settings and the comparators used (Avellar et al., 2017). For the purposes of this systematic review the assessment and reporting of internal validity (the risk of bias) are described in Section 4.14.1 and the assessment of external validity is reported via adherence to the PRISMA 2009 statement throughout the conduct and within the presentation of this systematic review (Moher et al., 2009) and as a narrative within the study characteristics section (see Section 4.14.2).

4.10.1 Risk of Bias within and across studies

Quality appraisal of studies included in reviews is important to ensure that the findings of trials are discussed transparently and appropriately, with the potential for any bias present in the conduct of trials to be ascertained prior to discussing the findings of a review (Jorgensen et al., 2016). Bias occurs when the results of a trial are subject to a systematic error and according to Higgins et al. (2011) the types of bias are categorised into the following domains: random sequence generation; allocation sequence concealment; blinding of participants and personnel; blinding of outcome assessment; incomplete outcome data; selective outcome reporting and finally other sources of bias. Any bias involved in a reviewed study can significantly affect the value of the reported outcomes and conclusions, which has the potential for far-reaching consequences, as systematic reviews and meta-analyses are used to guide best practice in healthcare (Joregensen et al., 2016).

The tool chosen to appraise the included studies for bias during this review was the Risk of Bias tool, version 1, as developed by The Cochrane Collaboration for systematic reviews (Higgins and Green, 2011). This tool was recommended by the Cochrane Collaboration's handbook for the conduct of systematic reviews as the gold standard for assessing the risk of bias (Higgins and Green, 2011). Whilst other scales have been developed to assess methodological quality of studies, such as the Jadad Scale (Jadad et al., 1996), it is the Cochrane Collaborations Risk of Bias tool that is most used in published reviews and remained the gold standard at the time of conducting the systematic review (Jorgensen et al., 2016). Application of the Risk of Bias tool provides an objective measure of the extent to which bias, such as participant or site selection, reporting or attrition, has contributed to the findings reported; an important consideration when considering the efficacy of the treatment(s) being trialled (Higgins and Green, 2011). To appraise the studies' risk of bias, the tool (Higgins and Green, 2011) was applied to each of the studies individually at the point of data extraction. Following data extraction, application of the tool (Higgins and Green, 2011) was conducted as instructed, which was to provide a judgement of the extent to which published studies contained bias in relation to the domains listed.

Reflective Diary Excerpt

A new version of the Risk of Bias tool (Risk of Bias, v2; Sterne et al., 2019) has been developed in the time between the completion of the systematic review and the submission of this thesis (August 2019 and the last updated literature search for inclusion was July 2019). I debated prior to the submission of the thesis, what would be gained from re-evaluating the potential for bias in the incorporated review, however I decided this wasn't appropriate because a) the outcome of the review had already influenced the subsequent phases of this PhD and b) it would not increase the value [validity] of the included studies, or thus change the outcome of the review. Following careful consideration and including a recommendation from the Cochrane Handbook (Higgins et al., 2019) that reviews should only be updated if there was a practical benefit to the outcomes, it was decided that the original version, which influenced the subsequent phases of this PhD would remain within the reporting of this systematic review and meta-analyses and no change should occur, including the application of the Risk of Bias.

4.10.2 Summary measures

Summary measures expected are changes in mean outcome measure score over time. The measurement of psychosis symptoms (outcome) within studies must have been completed using a validated outcome measure. Measures predominantly used in both clinical practice and clinical research study designs to ascertain psychotic symptoms are the Brief Reactive Psychiatric Scale (BPRS) (Overall and Gorham, 1962), the Positive and Negative Syndrome Scale (PANSS) (Kay et al., 1987) and both the Clinical Global Impressions Scale (CGI) (Guy, 1976) and the Clinical Global Impressions Scale for Schizophrenia (CGI-SCH) (Haro et al., 2003). The CGI and CGI-SCH records an individual clinician’s view on the patient at the point of first presentation and then the patient’s treatment response is measured against a clinician’s view at subsequent phases. The CGI and CGI-SCH measures are not appropriate for clinical trials because participants will already have had a first presentation and have baseline assessment data collected by a clinician before being consented to participate in the trial and as that clinician is unlikely to conduct all future assessments for them there is the potential for systematic error to be introduced.

4.11 Synthesis of results

The systematised review of peer-reviewed evidence can include the statistical combination of data from different studies, in order to produce an effect size from a larger pool of participants, which is termed a meta-analysis (Crowther et al., 2010). The benefit of a meta-analysis is that the application of a valid statistical test to a larger pool of participants deems the result less susceptible to type-2 error, meaning that the result is more likely to detect any ‘difference’ in the effect of the intervention that may exist between the two groups (Crowther et al., 2010). For meta-analysis to be appropriate, however, there must be sufficient homogeneity in the key variables, namely: population, intervention, comparison and outcome(s) (Crowther et al., 2010). There were two diet supplements, namely the amino acid lysine and omega-3 fatty acids, where they had sufficient homogeneity in terms of these key variables to support respective meta-analyses.

Reflective diary excerpt

From a Pragmatist perspective, it was difficult to decide whether to conduct the two meta-analyses completed and presented as part of this PhD. There was, on the one hand, sufficient homogeneity in terms of PICO for these to be warranted, however due to the potential uncertainty in terms of risk of bias, the results may need to be interpreted with caution. I decided, that as the PhD is not just about research, it is also about training, that these should be undertaken, but interpretation of the resultant effect sizes must be done in conjunction with the outcomes of the risk of bias assessment.

4.11.1 Meta-analysis methods

There were two potential methods that could be used to synthesise data within a meta-analysis: the fixed effects method and the random effects method (DerSimonian, 1986). The random effects method was chosen due to an expectation of heterogeneity in study effects. The decision for which to choose was based on the heterogeneity that exists between studies and thus the two methods would give the same result if no heterogeneity were present (Higgins and Green, 2011). The fixed effects method assumes that studies included in the pooled analysis all have equal interventional effects, however the random effects model expects that study effects will be different (heterogeneous) (Higgins and Green, 2011).

4.11.2 Meta-analysis data

For the meta-analyses conducted as part of this review, the post-interventional difference in means between treatment and placebo group and respective standard deviation was used in conjunction with the random effects method (DerSimonian, 1986) to generate a pooled difference in means thereby maximising the cumulative effect of all participants included in the studies. The results of the meta-analysis are presented within the narrative and represented as Forest plots, which are a standard method used to graphically represent the findings of meta-analyses (Higgins and Green, 2011).

4.11.3 Missing data

Two of the studies which met the review's inclusion criteria (See Section 4.3.1, Table 4.1) were excluded from the review on the basis that they did not report sufficient data in relation to the primary outcome of psychosis symptoms. The lead authors of both papers were contacted as recommended by the Cochrane Consumers and Communication Review Group in cases of missing data (Prictor and Hill, 2013) via the contact emails listed on the publication, however no responses were received.

Additional calculations were required to provide missing data: the necessary standard deviation results essential to pooled analysis. Of the 4 studies included in the meta-analyses (two meta-analyses conducted, comprising two studies each), one required manual calculation of the standard deviation (Zeinoddini et al., 2014), one presented the standard error of the mean (thus requiring one additional calculation) (Pawelczyk et al., 2016), one presented t-value data (requiring two additional calculations) (Jamilian et al., 2014) and one presented p-value data (requiring three additional calculations) (Wass et al., 2011). The calculations were performed using the necessary formulae, as cited in the Cochrane Handbook (Higgins and Green, 2011), and are listed in Appendix 4.

The two meta-analyses were conducted using the Cochrane Collaboration's Review Manager Version 5.3 for windows (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014), which is a software package specifically designed by the Cochrane Collaboration to support meta-analyses of this type and can generate Forest plots. There has been debate on the minimum number of studies to warrant a meta-analysis (Schriger et al., 2010), however the Cochrane Collaboration indicated that two studies was acceptable providing they were sufficiently homogenous and that pooling their results would add meaning (Friede et al., 2017). The decision was taken that the potential outcome generated from meta-analyses from two studies could generate knowledge helpful to meeting the aim of this systematic review.

4.11.4 Additional analyses

Where sufficient data exists, additional analyses can be conducted for sub-groupings, for factors such as gender, age or diagnostic nuances (Crowther et al., 2010), however for these analyses to be meaningful, there must be data from a sufficiently large sample to provide the statistical power required (Suresh and Chandrashekara, 2012). Due principally to the heterogeneity of the trial agents across the nine included studies and the consistently small sample sizes used (see Section 4.13, Table 4.3), no sub-analyses of the data were considered or conducted.

4.12 Results

4.12.1 Study selection

4.12.1.1 Main search (2017) results

The main database search returned a total of 31,840 citations with a publication year between 2005 and 2017 (inclusive). All citations were subject to a filter to identify those not published in the English language; this identified and removed 1,041 citations. The remaining citations (n= 30,799) were imported into the Covidence software program (Covidence systematic review software, Veritas Health Innovation, Melbourne, Australia. Available at www.covidence.org), which is specialist software designed to support citation screening and management. The use of Covidence facilitated the screening process through the automatic removal of duplicated records and facilitated the researcher in screening large volumes of citation titles against the inclusion and exclusion criteria. The researcher could check a box and citations were then logged as included or excluded based upon specific criteria. This provided assurance on the screening process by allowing the researcher to go back and make quality checks on included and excluded citations.

Upon importation to Covidence (Covidence systematic review software, Veritas Health Innovation, Melbourne, Australia. Available at www.covidence.org.), there were 7,255 citations removed automatically as duplicates. The remaining 23,544 citations were screened manually by the researcher and a further 9,689 were removed as duplicates. The remaining citations (n= 13,855) were screened by the researcher against the inclusion and exclusion criteria based on their title. A total of 485 citations warranted abstract screening following the initial title screening process and 148 citations warranted full text screening against inclusion and exclusion criteria. This resulted in 11 studies to be subject to data extraction, of which nine contained sufficient data to warrant inclusion in the review.

4.12.1.2 Updated search (July 2019) results

Due to the time taken to conduct the initial search, citations screening and data extraction, a decision was taken to update the literature search prior to the final production of results and outcomes from the review. This decision was taken as part of a Pragmatic approach to make sure that the outcomes produced were up to date and provided the best evidence prior to conducting the subsequent phases of this PhD. The updated search was conducted in July 2019 using the same search terms as the main search conducted in 2017 for citations published between 2017 and 2019 (inclusive). This returned an additional 230 citations, which were screened by title against the inclusion and exclusion criteria manually, with seven citations requiring abstract screening, of which two were screened by full text. This resulted in one additional study for inclusion within the systematic review. The combined metrics from the search are reported according to the PRISMA guidelines (Moher et al., 2009), as detailed in the PRISMA checklist (see Appendix 5) and presented in the PRISMA flow diagram (Figure 3, below):

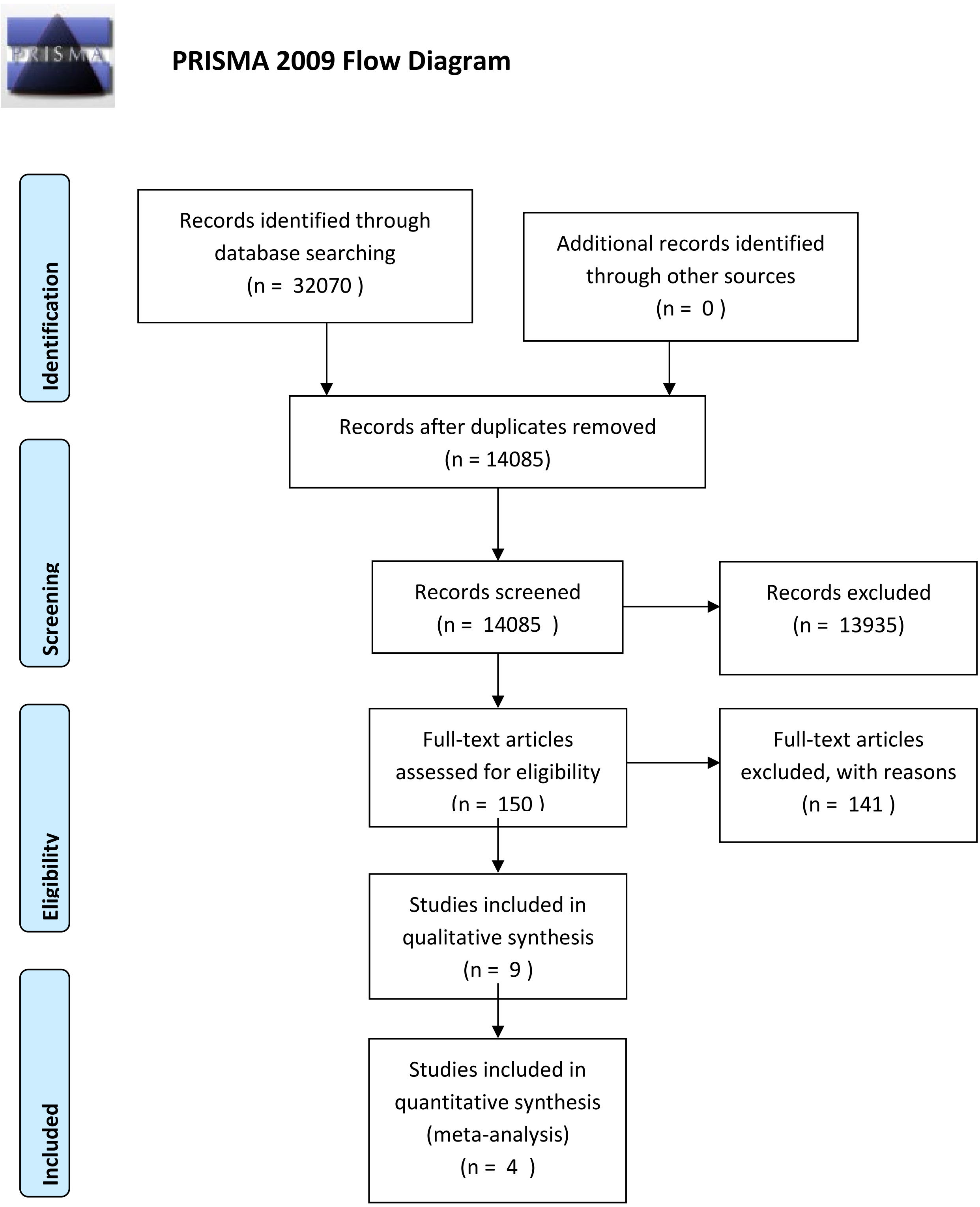

Figure 3: PRISMA flow diagram detailing citation review and included studies

4.12.2 Quality Control during citation screening process

A proportion of the 492 abstracts were screened independently by a second reviewer from the Supervisory Team. Screening started with the first paper from the alphabetised list of abstracts, and then every subsequent 20th paper was screened. This gave a total of 24 abstracts. The results of both the lead reviewer and the secondary reviewer highlighted that there were six papers where a discussion was required on whether or not these studies met the inclusion criteria. A discussion of the six papers was had and following discussion the second reviewer agreed with the original decision and a consensus was reached. All six of the studies where discrepancies were noted had failed to meet the inclusion criteria pertaining to the active management of psychotic symptoms.

4.12.3 Characteristics of citations screened as full-text studies

All studies that met the inclusion criteria based upon screening of the abstract (n=150) were screened against their full text and these were accessed either through open access online (n=83), or through both the University's library portal and NHS Library service (n=67). Of the 150 papers screened at full text, there were 126 that did not meet the required study type inclusion criteria (See Table 4.2 for more information), leading to 24 RCT studies remaining for full text review. Of these 24 RCTs, seven were rejected due to trialled agents being formed through de novo synthesis and not consumed orally, therefore not meeting the definition of a dietary or nutritional intervention (see introductory chapter, section 1.3) and three were rejected due to the study outcome not measuring being symptoms of psychosis. Additionally, three were rejected due to inclusion of participants under the age of 14 (n=2) or over the age of 65 (n=1), which resulted in 11 papers remaining for data extraction. Contacts with the authors was not successful resulting in the 2 studies being removed from the review resulting in nine studies for inclusion.

Table 4.2: Methodological characteristics of studies excluded following full text screening

Methodological/Publication type	**Number**
Letters to Editors, Poster/Conference, Abstracts, Clinical Guidelines	23
Case Reports or Case Series	16
Case: Control Studies	6
Open-label Pilot study	2
Review	79
RCT	24
TOTAL	**150**

4.13 Study characteristics

Nine studies were included and their characteristics, including country of origin, sample size and nutritional dosing regimen are listed in Tables 4.3 and 4.4. All studies trialled the efficacy of nutrients in the form of dietary supplements, and none trialled the efficacy of nutrients as part of whole foods. All were RCTs, with two applying a crossover design (Kapstan et al., 2007; Wass et al., 2011). As shown in Table 4.3, six of the studies recruited participants with a diagnosis of schizophrenia, two recruited first episode psychosis patients (O'Donnell et al., 2016 and Pawelczyk et al., 2016) and one recruited those with either a diagnosis of schizophrenia or schizoaffective disorder (Ritsner et al., 2011). Of the nine studies included, only seven reported study setting, which ranged from community (n=3), inpatient (n=1) and both community and inpatient mixed (n=3) and spanned three continents: Europe (n=2), Asia (n=6) and Australasia (n=1).

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Table 4.3: Summary of included studies' characteristics

Study	**Country**	**Sample size (treatment n: placebo n)**	**Diagnosis**	**Age Range (years)**	**Co-morbid Substance abuse**	**Setting**
Kapstan et al., 2007	Israel	12 (6:6)	Schizophrenia	27 - 54	Excluded	N R
Wass et al., 2011	Sweden	10 (10:10)	Schizophrenia	23 - 56	Excluded	Community
Zeinoddini et al., 2014	Iran	80 (40:40)*	Schizophrenia	18 - 50	Excluded	Inpatient
Ritsner et al., 2011	Israel	60 (30:30)	Schizophrenia or Schizoaffective Disorder	19 - 55	Excluded	Mixed
O'Donnell et al., 2016	Australia	86 (47:39)*	First Episode Psychosis	18 - 25	Excluded	Community
Jamilian et al., 2014	Iran	60 (30:30)	Schizophrenia	15 - 55	Excluded	N R
Pawelczyk et al., 2016	Poland	71 (36:35)*	First Episode Schizophrenia	16 - 35	N R	Mixed
Dhakale et al., 2005	India	40 (20:20)	Schizophrenia	Adult (N R)	N R	Community
Krivoy et al., 2017	Israel	47 (24:23)*	Schizophrenia	18 - 65	N R	Mixed

The nutrients trialled (see Table 4.4) comprised four different amino acids: creatine, lysine, theanine and taurine, investigated through five separate studies (Kapstan et al., 2007; Wass et al., 2011; Zeinoddini et al., 2014; Ritsner et al., 2011; O'Donnell et al., 2016). Omega-3 fatty acids were investigated in two studies (Jamilian et al., 2014; Pawelczyck et al., 2016). The remaining nutrients were vitamins: Vitamin C (Dhakale et al., 2005) and Vitamin D (Krivoy et al., 2007). The authors' rationale for trialling these individual nutrients is summarised in Table 4.4

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Table 4.4: Summary of Study treatment agents with details of administration, dosage rate and study attrition rates

Study Citation	Nutrient (s) Name	Nutrient (s) Description	Rationale for its efficacy in psychosis management	Adjunctive or Standalone	Dose	Admin. method	Frequency	Duration	Placebo	Diet recording reported	Biochemical indices	Attrition rate
Kapstan et al., 2007	Creatine	Amino Acid	Creatine is essential component in brain homeostasis and may enhance cognition in schizophrenia	Adjunctive	5g (3g 0-4 weeks)	Capsules	Daily	3 months	N R	N R	N R	17%
Wass et al., 2011	Lysine	Amino Acid	Nitric Oxide signalling system in the brain linked to schizophrenia and is inhibited by Lysine	Adjunctive	6 g	Soft drink	Daily	4 weeks	N R	N R	Yes	10%
Zeinoddini et al., 2014	Lysine	Amino Acid	Nitric Oxide signalling system in the brain linked to schizophrenia and is inhibited by Lysine	Adjunctive	6 g	Capsules	Daily (2x1gx3 times daily)	8 weeks	N R	N R	N R	10%
Ritsner et al., 2011	Theanine	Amino Acid	Theanine has neuroprotective and neuromodulatory properties, including in relation to neurotransmission	Adjunctive	400 mg	Capsules	Daily (2x200mg)	8 weeks	N R	N R	Yes	33%
O'Donnell et al., 2016	Taurine	Amino Acid	Taurine acts as a neuroprotective and neuromodulatory agent	Adjunctive	4 g	Not reported	Daily	12 weeks	N R	N R	N R	29%
Jamilian et al., 2014	Omega-3	Fatty Acid	Omega-3 fatty acids may improve neurotransmission and enhance efficacy of antipsychotic medicines	Adjunctive	1000 mg	Capsules	Daily	8 weeks	N R	N R	N R	N R
Pawelczyk et al., 2016	Omega-3	Fatty Acid	Essential nutrient often deficient in those with schizophrenia	Adjunctive	2.2 g	Capsules	Daily	26 weeks	Yes; olive oil	N R	N R	8%
Dhakale et al., 2005	Vitamin C	Vitamin	Act as an antioxidant that would improve free-radical medicated pathology in schizophrenia	Adjunctive	500 mg	Capsules	Daily	8 weeks	N R	N R	Yes	13%
Krivoy et al., 2017	Vitamin D	Vitamin	Low Vitamin D status associated with psychosis	Adjunctive	14000 IU	Oral Drops	Daily	8 weeks	N R	N R	Yes	11%

All included studies considered the efficacy of the trial agent on the symptoms of psychosis as the primary outcome of their trial. All nine studies considered mono-nutrient dietary supplements and all groups in the included studies received treatment or placebo as an adjunct to psychotropic medication and standard medical care (see Table 4.4). Seven studies determined the presence of psychotic symptoms by using the Positive and Negative Syndrome Scale (PANSS) (n=7) and two studies (Dhakale et al., 2005; O' Donnell et al., 2016) used the Brief Psychiatric Reporting Scale (BPRS).

4.14 Quality Appraisal of included studies

4.14.1 Internal validity results: Risk of bias within studies

The results of the application of the Risk of Bias tool (Higgins and Green, 2011) are presented in Table 4.5. Quality of reporting/data presentation and analysis is heterogeneous between studies and the risk of bias was predominantly unclear across the studies due to a lack of information given in the publication. The methods used and the detail of reporting of randomisation and blinding was variable between studies, as indicated in Table 4.5. The roles of the study team members, with regard to which personnel were involved in the randomisation of participants and which personnel collected measures, was under-reported in all studies.

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Table 4.5: Risk of Bias assessment of included studies

Study citation	**Risk of Bias Domain**					
	Selection bias - random sequence generation	Selection bias - Allocation concealment	Performance bias - blinding of participants and personnel	Detection bias - blinding of outcome assessment	Attrition bias - incomplete outcome data	Reporting bias - selective reporting
Kaptsan et al., 2007	Unclear	Unclear	Low	Low	Unclear	Unclear
Wass et al., 2011	Unclear	Unclear	Unclear	Unclear	Low	Unclear
Zeinoddini et al., 2014	Low	Low	Low	Unclear	Unclear	Low
Ritsner et al., 2011	Low	Unclear	Low	Unclear	Low	Low
O'Donnell et al., 2016	Unclear	Low	Low	Low	Low	Low
Jamilian et al., 2014	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Pawelczyk et al., 2016	Low	Low	Low	Low	Low	Unclear
Dhakale et al., 2005	Low	Low	Unclear	Unclear	Unclear	Unclear
Krivoy et al., 2017	Low	Low	Low	Low	Unclear	Unclear

None of the studies were assessed as at high risk of bias, following application of the Risk of Bias tool and all remaining studies had at least one domain where the potential for bias was unclear due to insufficient information reported to ascertain it. Included studies that are rated ‘unclear’ as to their potential for bias may be subject to some systematic error in terms of study conduct, although all or some of those may also have avoided bias in their conduct and the limitation sits with the accuracy of the authors’ reporting in the respective peer-reviewed journal (Higgins and Green, 2011). This represents a limiting factor by which both the individual and synthesised results of these studies and consequent findings from the systematic review should be judged.

4.14.2 External validity: factors affecting the generalisability of the results

4.14.2.1 Sample size

As indicated in Table 4.3, all of the included studies had small sample sizes (range: 10-86) and none presented a power calculation to determine whether their sample size had sufficient power to detect a significant effect from the trial agent. The reported findings may, therefore be restricted in terms of applicability more widely to adults with psychosis. For two of the nutrients contained in the diet supplement studies: omega-3 fatty acids and the amino acid Lysine, a pooled analysis for two studies from each nutrient group were conducted which increased the sample size to 131 for omega-3 fatty acids and 92 for lysine.

4.14.2.2 Study Characteristics

a) Population

All included studies reported samples comprising adults aged 14 to 65 at the time of participation, with a diagnosis indicating a psychotic disorder, as these were inclusion criteria for the review. All studies presented basic demographic characteristics of their participants (see Table 4.3), such as gender and age at time of participation, however due to the small sample sizes sub-analyses or additional inferences based on these features were not possible. It is unclear therefore whether the effects of the trialled agents differed between genders or within different age groups.

Six of the studies had excluded participants with known co-morbid substance misuse issues (Kapstan et al., 2007; Wass et al., 2011; Ritsner et al., 2011; Jamilian et al., 2014, Zeinoddini et al., 2014, O’ Donnell et al., 2016), with the remaining three studies not reporting whether participants with co-morbid substance use disorders were included or excluded. This characteristic of the included studies is noteworthy in relation to the development of a diet-related intervention for psychosis management, because the intervention should be of value to all individuals aged 14 to 64 experiencing psychosis. It has long been evident that a proportion of those with schizophrenia will have a co-morbid substance abuse issue, with a recent meta-analysis reporting a rate of co-morbid substance use disorder at 42% (Hunt et al., 2018). The findings of the studies which excluded participants with known history of substance use (Kapstan et al., 2007; Wass et al., 2011; Ritsner et al., 2011; Jamilian et al., 2014, Zeinoddini et al., 2014, O' Donnell et al., 2016) may not be representative of almost half (42%) of those with schizophrenia and therefore may not be generalisable.

b) Trialled agent

Sufficient information was provided on the nature of the diet supplements provided and their dosing regimen for this to be repeated. Only one study reported that they had collected dietary intake data at baseline, however the authors did not report the outcomes of the dietary assessment within the publication. As the trialled agents for all studies were nutritive, it would have been prudent to ascertain firstly a baseline level of the trialled nutrient that was acquired through the diet and assess the dietary intake of the trialled nutrient throughout the dosing period. The diet of individuals could be significantly different at the trial baseline from the population norm or may have altered during the trial. This could have occurred either through chance or through acquiring food knowledge via active participation in a dietary trial, which is associated with altered eating behaviour (Scaglioni et al., 2018). This represents a serious flaw in all of the included studies and goes beyond reporting bias as it may invalidate all of the findings related to the effect of the trialled agent(s).

c) Attrition rates

Attrition rates were reported for all but one of the studies (see Table 4.4), however the reasons for attrition were poorly documented in these studies. The attrition rates ranged between 8% and 33%, with at least two of the studies' attrition rates (O' Donnell et al., 2016 and Ritsner et al., 2011) representing high levels of attrition at almost one third of total participants. This is noteworthy as attrition may represent a trialled supplement that was unacceptable to participants from factors, such as taste or side effects.

d) Setting

The included studies represented populations drawn from a range of settings, including community, inpatient and mixed residences, although two (Kapstan et al., 2007 and Jamilian et al., 2014) failed to report details of the settings included.

e) Comparators used

All of the studies administered a placebo as a comparator against the trialled dietary supplement. The reporting of the nature of placebos varied across the studies. Only one study (Pawelczyk et al., 2016) provided sufficient details and a clear scientific justification of the placebo used for their RCT. This placebo was olive oil, with an insignificant amount of fish oil in a gel capsule, to match the smell and taste with the trial agent (Pawelczyk et al. 2016). The justification for the use of olive oil was that it contained mostly monounsaturated fatty acids and few polyunsaturated fatty acids that had been used successfully in other similar studies (Pawelczyk et al., 2015) and the inclusion of a small amount of fish oil was required to give the placebo a comparable taste and smell to the trial agent (Pawelczyk et al., 2016).

The remaining eight studies listed no details on the nature of the placebo, in terms of the supplemental agent used. This represents an issue in terms of the quality of the trial reporting because there is the potential that the placebos used also contained nutrients, which may have impacted on the results. A standard placebo for drugs trials, is to use either starch or sugar, for example, however these are clearly a source of nutrients and may impact on the absorption and thus effect of trialled diet supplements.

4.14.3 Synthesised results

There were no studies which trialled the efficacy of a whole food(s) over standard treatment; all of the included studies trialled nutrients in the form of dietary supplements (see Table 4.4). There was heterogeneity in the type of nutrients trialled, with nutrient types spanning macronutrients (amino acids and fatty acids) (Kapstan et al., 2007; Wass et al., 2011; Ritsner et al., 2011; Jamilian et al., 2014; Zeinoddini et al., 2014; O'Donnell et al., 2016 and Pawelczyck et al., 2016) and micronutrients (vitamins) (Dhakale et al., 2005; and Krivoy et al., 2017). It is deemed inappropriate to combine a variety of different nutrients into one meta-analysis because they are too heterogeneous in nature, with differences including source foods and mechanisms of action (Barnard et al., 2017). For this reason, the totality of individual nutrients could not be pooled to give one resultant effect size. The following nutrient sub-groupings were used to facilitate the reporting and discussion of findings: omega-3 fatty acids, amino acids and vitamins.

The primary outcome measure for this review was the variance in total symptoms of psychosis post-intervention compared to baseline, as assessed by a validated outcome measure. The results from the nine included studies are presented in Table 4.6 below.

Table 4.6: Variance in total psychosis symptoms for included studies

Study		Kapstan et al., 2007&	Wass et al., 2011&	Zeinoddini et al., 2014	Ritsner et al., 2011	O'Donnell et al., 2016		Jamilian et al., 2014	Pawelczyk et al., 2016	Dhakale et al., 2005	Krivoy et al., 2017
Outcome measure		PANSS	PANSS	PANSS	PANSS	PANSS	BPRS	PANSS	PANSS	BPRS	PANSS
Score (+/- SD)											
Baseline	Treatment	64.7 (+/- 5.1)&	69.2 (+/-4.7)	105.33 (+/- 14.00)	78.5*	61.3 (+/- 17.1)	46.5 (+/- 14.3)	96.13 (+/- 9.61)	98.4 (+/-13.22)	36.65 (+/- 5.78)	81.8 (+/- 9.2)
	Placebo	64.3 (=/- 4.5)&	69.2 (+/-4.7)	105.61 (+/- 13.94)	86.1*	65.4 (+/- 17.0)	48.6 (+/- 14.4)	98.26 (+/- 4.51)	96.8 (+/- 12.01)	35.9 (+/- 5.41)	87.4 (+/- 13.7)
Post-intervention	Treatment	N R	65.2 (+/-5.4)	N R	54.6*	N R	N R	49.13 (+/- 5.31)	N R	19.30 (+/- 5.46)	N R
	Placebo	N R	63.1 (+/-5.0)	N R	65.9*	N R	N R	52.43 (+/- 3.32)	N R	28.96 (+/- 6.16)	N R
Mean score difference	Treatment	2.2 (+/-1.8)	4.0*	52.50 (+/- 12.11)	23.9*	8.3 (+/-12.4)	8.5 (+/-10.7)	47.0^	19.27 (+/-1.38)	14.79 (+/- 4.87)	8.9 (+/-7.3)
	Placebo	0.6 (+/-1.5)	6.1*	39.17 (+/- 13.41)	20.2*	3.8 (+/-11.6)	4.0 (+/-10.3)	45.83^	14.42 (+/-1.4)	6.93 (+/- 4.82)	10 (+/- 10.2)
Statistical test applied to determine primary outcome		ANOVA	ANOVA	General Linear Model with Repeated Measures	ANOVA	ANCOVA	ANCOVA	GEE population-averaged model	Mixed Model for Repeated Measures (MMRM).	Unpaired t-test	General Linear Model with Repeated Measures
Significance of result (change over time), as reported		F(1.8) = 0.24; p=0.6; in favour of placebo	F(NR) = 13.36; p=0.002; in favour of placebo	F(1.96) = 12.10; p<0.001; in favour of **treatment**	not reported for total symptoms; only reported for symptoms subscales	mean difference = 4.7; 95% CI: 0.1 - 9.4; p=0.052; in favour of treatment	mean difference = 5.2; 95% CI: 1.8 - 8.5; p=0.004; in favour of **treatment**	Coef = 0.86; SE=0.717; Z=1.2; 95% CI: -0.546) p=0.231; in favour of treatment	Least Squares mean difference = -4.84; 95% CI: -8.77 to -0.92; p<0.05 in favour of **treatment**	T(NR); p<0.01; in favour of **treatment**	z(45) = 0.45; p=0.65; in favour of placebo

Key

& represents a crossover design

* Not reported clearly; this value was obtained by totalling the reported values for the three subscales

^ Not reported; this value was obtained by calculating the difference between mean scores at two timepoints

Underlined text represents the group favoured by the outcome and **emboldened** text represents a reported significant result

As indicated in Table 4.6, of the nine included studies, seven assessed psychosis symptoms using the PANSS, one with the BPRS and one used both measures. There was variation in the reporting of outcome measure scores, with all but one study presenting the baseline values for both treatment and placebo groups, whereas only three studies presented the post-intervention values. Six of the studies presented the mean score change values for the treatment and placebo groups. A range of statistical tests were used for analyses by studies (see Table 4.6), including ANOVA (n=3), t-test (n=3), ANCOVA (n=1), MMRM (n=1) and the GEE population averaged model. Five of the nine studies reported main results for efficacy of trialled agent against placebo that favoured the treatment (see Table 4.6), of which four were reported as significant (see Table 4.6). The one study (see Table 4.6) that presented results for efficacy of the trialled dietary supplement against placebo for total symptoms of psychosis as assessed by two different validated measures reported both as favouring the treatment, although only one result was valid (assessment of symptoms using the BPRS). Two studies reported results that favoured the placebo, although neither were significant (see Table 4.6) and one study did not report against the outcome of the trialled diet supplement versus placebo against total symptoms of psychosis (see Table 4.6).

4.15 Results of individual studies, presented by diet supplement group

4.15.1 Amino acids

4.15.1.1 Lysine

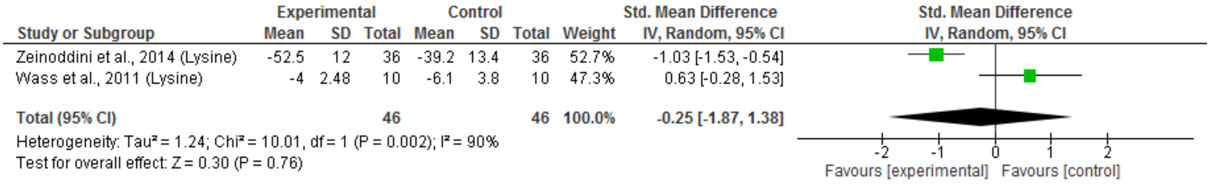
a) Individual study findings

Two studies trialled the efficacy of providing Lysine (L-lysine) versus placebo on psychosis symptoms, with dosing regimens as 6g/day for four weeks administered via a soft drink (Wass et al., 2011) and 6g/day for eight weeks as capsules (2 x 1g capsules, 3 x per day) (Zeinoddini et al., 2014). Wass et al. (2011) used one- or two-way ANOVA, as appropriate and performed Bonferroni correction to results. Zeinoddini et al., (2014) used the General Linear Model with repeated measures to compare score mean differences in changes from baseline to end of intervention.

Full details are presented in Table 4.6, however in summary, Wass et al. (2011) presented a mean difference to total symptoms of psychosis favouring placebo. This was based on PANSS score, between the two groups post-baseline following 4 weeks intervention with Lysine (mean total PANSS score improvement of 4.0 (treatment) compared with 6.1 (placebo), which was significant (F(NR) = 13.36; $p<0.002$) (Wass et al., 2011). Zeinoddini et al., (2014), however, reported that both treatment and placebo groups had demonstrated a significant reduction in mean total symptoms based on PANNS scores (reduction of 52.50 (in treatment group and 39.17 in placebo), which represented a significant improvement in mean total PANSS score between the two groups, in favour of the treatment group (F(1.96) = 12.10; p<0.001). The authors also reported a significant improvement to negative (F(2.01) = 14.46; p<0.001) and general symptoms (F(1.86) = 9.20; p<0.001), based on PANSS subscales, for treatment over placebo, but not with positive symptoms (F(2.56) = 0.56; p<0.61) (Zeinoddini et al., 2014).

b) Pooled study findings

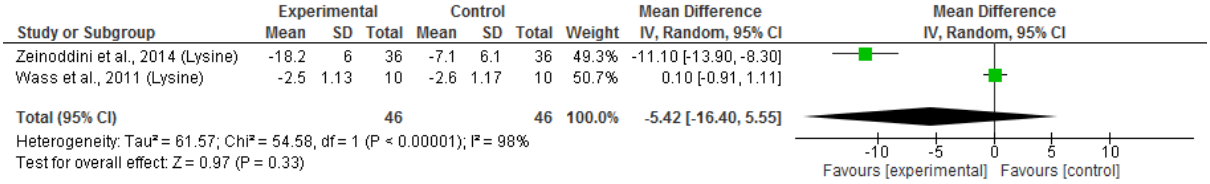
The pooled results from trials of lysine (n=2; pooled sample n=92 (46:46)) (Wass et al., 2011 and Zeinoddini et al., 2014) showed no significant improvement in total symptoms of psychosis versus placebo (-0.25 [-1.87, 1.38] (Z=0.30; p=0.76) (See Figure 4). This result was set in the context of high heterogeneity (I^2 = 98%). A similar result was noted for positive (mean difference = -5.42 [-16.40, 5.55]; Z=0.97; p=0.33), negative (mean difference = -1.91 [-6.82, 3.00]; Z=0.76; p=0.45) and general (mean difference = -2.54 [-11.30, 6.22]; Z=0.57; p=0.57) psychosis symptoms (See Figures 4 - 7).



Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Zeinoddini et al., 2014 (Lysine)	-52.5	12	36	-39.2	13.4	36	52.7%	-1.03 [-1.53, -0.54]
Wass et al., 2011 (Lysine)	-4	2.48	10	-6.1	3.8	10	47.3%	0.63 [-0.28, 1.53]
Total (95% CI)			**46**			**46**	**100.0%**	**-0.25 [-1.87, 1.38]**

Heterogeneity: Tau² = 1.24; Chi² = 10.01, df = 1 (P = 0.002); I² = 90%
Test for overall effect: Z = 0.30 (P = 0.76)

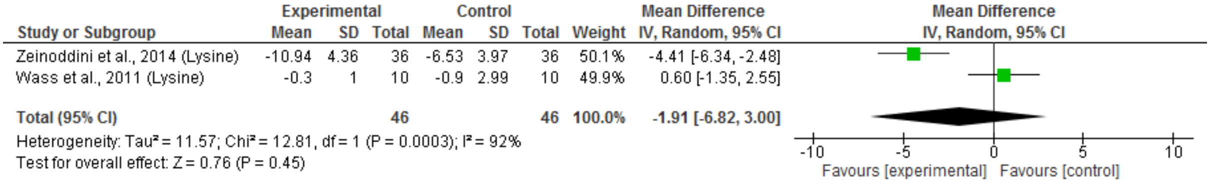
Figure 4: Variance in <u>Total</u> symptoms of Psychosis from the meta-analysed data (n=2 studies) following intervention with Lysine



Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Random, 95% CI
Zeinoddini et al., 2014 (Lysine)	-18.2	6	36	-7.1	6.1	36	49.3%	-11.10 [-13.90, -8.30]
Wass et al., 2011 (Lysine)	-2.5	1.13	10	-2.6	1.17	10	50.7%	0.10 [-0.91, 1.11]
Total (95% CI)			**46**			**46**	**100.0%**	**-5.42 [-16.40, 5.55]**

Heterogeneity: Tau² = 61.57; Chi² = 54.58, df = 1 (P < 0.00001); I² = 98%
Test for overall effect: Z = 0.97 (P = 0.33)

Figure 5: Variance in <u>Positive</u> symptoms of Psychosis from the meta-analysed data (n=2 studies) following intervention with Lysine



Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Random, 95% CI
Zeinoddini et al., 2014 (Lysine)	-10.94	4.36	36	-6.53	3.97	36	50.1%	-4.41 [-6.34, -2.48]
Wass et al., 2011 (Lysine)	-0.3	1	10	-0.9	2.99	10	49.9%	0.60 [-1.35, 2.55]
Total (95% CI)			**46**			**46**	**100.0%**	**-1.91 [-6.82, 3.00]**

Heterogeneity: Tau² = 11.57; Chi² = 12.81, df = 1 (P = 0.0003); I² = 92%
Test for overall effect: Z = 0.76 (P = 0.45)

Figure 6: Variance in <u>Negative</u> symptoms of Psychosis from the meta-analysed data (n=2 studies) following intervention with Lysine

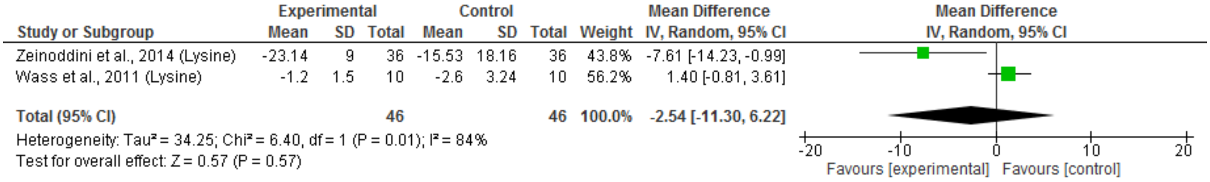


Figure 7: Variance in General symptoms of Psychosis from the meta-analysed data (n=2 studies) following intervention with Lysine

4.15.1.2 Creatine

One RCT trialled the efficacy of creatine in adults with schizophrenia (Kapstan et al., 2007) (n=12) administered at 5g daily versus a placebo over a period of three months, which included a crossover design. The dosing regimen was as follows: group 1 (n=6) were administered creatine for three months, followed by placebo for three months, whilst in parallel group 2 (n=6) were administered placebo for three months and then creatine for three months (Kapstan et al., 2007). ANOVA was performed for improvement scores for PANSS and its subscales and the treatment effect (within-subject comparison) and the treatment order effect (between-subject comparison) was calculated (Kapstan et al., 2007). The baseline mean PANSS scores were 64.7 (+/- 5.1) and 64.3 (+/- 4.5) for the treatment and placebo groups respectively and the authors reported an improvement in PANSS scores as 2.2 (+/- 1.8) and 0.6 (+/- 1.5) for the treatment and placebo groups respectively, which was not significant (F(1.8) = 0.24; p=0.6) (Kapstan et al., 2007).

4.15.1.3 Theanine

One RCT tested the efficacy of 400mg of L-theanine in adults (n=60; 30:30) with schizophrenia or schizoaffective disorder, versus placebo for a duration of 8 weeks (Ritsner et al., 2011). Statistical analysis of the PANSS rating scale was conducted using repeated-measures ANOVA using the general linear model and the Greenhouse-Geisser correction with three factors: 1) treatment condition, 2) time and 3) completers versus non-completers (Ritsner et al., 2011). Despite reporting that their primary outcome was total symptoms of psychosis, as indicated by the PANSS, the analyses presented were for the positive, negative and general subscales only (Ritsner et al., 2011). The results included a significant mean improvement in both the positive symptoms (F(1.236) = 6.9; p=0.09; an improvement in PANSS score of 4.6 treatment versus 3.5 placebo), and general symptoms (F(1.236) = 7.1; p<0.001; an improvement in PANSS score of 11.3 treatment versus 9.6 placebo), and a non-significant trend toward improvement in the negative symptoms (F(1.236) = 0.8; p=0.36; an improvement in PANSS score of 8.0 treatment versus 7.1 placebo).

4.15.1.4 Taurine

O'Donnell et al. (2016) reported their RCT trialling the efficacy of 4g/day taurine versus placebo for 12 weeks in adults (n=86; 47:39) aged 18 – 25 years diagnosed and treated for first episode psychosis. Variance in total psychosis symptoms, as measured by both PANSS and BPRS and assessed using ANCOVA, with multiple imputations used for missing values (O'Donnell et al., 2016). Total psychosis symptom improvement according to PANSS, was 8.3 (treatment) versus 3.8 (placebo), which showed a trend towards significance that favoured the treatment group (mean difference = 4.7; 95% CI: 0.1 – 9.4; p=0.052) (O'Donnell et al., 2016). Total psychosis symptom improvement according to the total BPRS was significant with a mean difference of 5.2 (95% CI: 1.8 – 8.5; p=0.004) A trend for improvement was shown in positive (mean difference = 1.3; 95% CI: -0.7 – 3.3; p=0.209), negative (mean difference = 0.9; 95% CI: -1.4 – 3.3; p=0.446) and general (mean difference = 2.7; 95% CI: 0.2 – 5.2; p=0.042) subscales of the PANSS (O'Donnell et al., 2016).

4.15.2 Omega-3 Fatty acids

4.15.2.1 Individual study findings

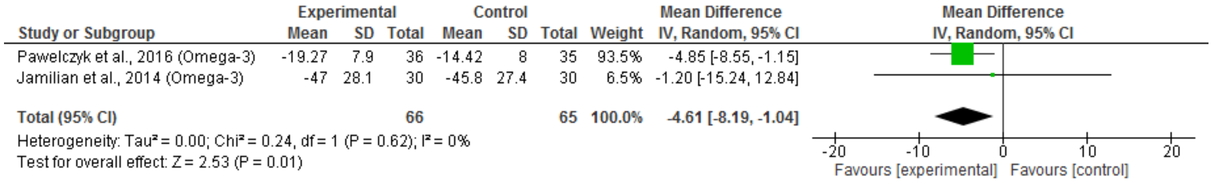
Two studies trialled omega-3 fatty acid efficacy (Jamilian et al., 2014 and Pawelczyk et al., 2016) one providing a dosing regimen of 2.2g of omega-3 fatty acids daily for 26 weeks versus placebo (Pawelczyk et al., 2016), whereas the other (Jamilian et al., 2014) trialled 1g omega-3 fatty acids versus placebo for 8 weeks. Neither study included any follow-up period. Data analysis method chosen (GEE population averaged model) was unclear for one study (Jamilian et al., 2014), which was reporting on a nested repeated measures (total, positive, negative and general PANSS symptoms. A mixed models repeated measures analysis was undertaken to assess the efficacy of the trialled agent against the primary outcome measure of the study (Pawelczyk et al., 2016).

Jamilian et al. (2014) reported that both the trial and placebo groups reported significantly improved total psychosis symptoms PANSS scores at 8 weeks compared to baseline (-47 points (treatment) and -45.83 points (placebo) (p<0.05). The difference in improvement to symptoms between the treatment and placebo groups at 8 weeks (-3.3 points), however as indicated by the GEE population-averaged model effect calculation was not significant (Coef = 0.86; SE=0.717; Z=1.2; 95% CI: -0.546; p=0.231). Pawelczyk et al. (2016) reported a significant improvement in total symptoms (based on PANSS score) in the treatment group compared to the placebo group (Least Squares (LS) mean difference = - 4.84; 95% CI: -8.77 to -0.92; p<0.05). Likewise, a significant improvement in general psychopathology symptoms (general

PANSS score) was reported from treatment over placebo (LS mean difference = -3.14; 95% CI: -5.46 - -0.83; p<0.01) (Pawelczyk et al., 2016). Improvement was noted in both positive (positive PANSS score) (LS mean difference = -1.09; 95% CI: -2.41 – 0.23; p=ns) and negative symptoms (negative PANSS score) from treatment over placebo (LS mean difference = -0.69; 95% CI: -1.97 - -0.6; p=ns) (Pawelczyk et al., 2016).

4.15.2.2 Pooled (meta-analysed) study findings

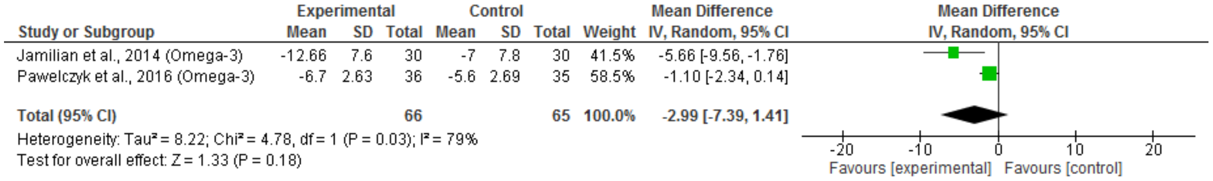
The results of the pooled sample analysis (study n=2; pooled sample n=131 (66:65)) demonstrated a significant beneficial effect from omega-3 fatty acid supplementation versus placebo for total symptoms of psychosis (-4.61 [-8.19, -1.04]; Z=2.53; p=0.01) (see Figure 8). A beneficial effect, although not statistically significant, was seen for positive (-2.99 [-7.39, 1.41]; Z=1.33; p=0.18), negative (-0.60 [-1.75, 0.55]; Z=1.03; p=0.30) and general (mean difference = -0.42 [-0.90, 0.05]; Z = 1.74; p=0.08) sub-scales of psychosis symptoms as determined by the PANSS (see Figures 8-11).



	Experimental			Control				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Pawelczyk et al., 2016 (Omega-3)	-19.27	7.9	36	-14.42	8	35	93.5%	-4.85 [-8.55, -1.15]
Jamilian et al., 2014 (Omega-3)	-47	28.1	30	-45.8	27.4	30	6.5%	-1.20 [-15.24, 12.84]
Total (95% CI)			**66**			**65**	**100.0%**	**-4.61 [-8.19, -1.04]**

Heterogeneity: Tau^2 = 0.00; Chi^2 = 0.24, df = 1 (P = 0.62); I^2 = 0%
Test for overall effect: Z = 2.53 (P = 0.01)

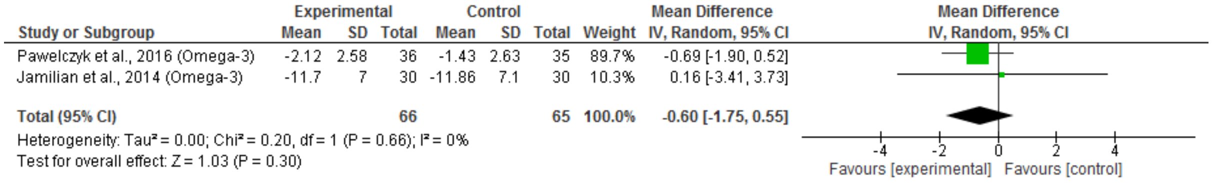
Figure 8: Variance in <u>Total</u> symptoms of Psychosis from the meta-analysed data (n=2 studies) following intervention with Omega-3 fatty acids



	Experimental			Control				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Jamilian et al., 2014 (Omega-3)	-12.66	7.6	30	-7	7.8	30	41.5%	-5.66 [-9.56, -1.76]
Pawelczyk et al., 2016 (Omega-3)	-6.7	2.63	36	-5.6	2.69	35	58.5%	-1.10 [-2.34, 0.14]
Total (95% CI)			**66**			**65**	**100.0%**	**-2.99 [-7.39, 1.41]**

Heterogeneity: Tau^2 = 8.22; Chi^2 = 4.78, df = 1 (P = 0.03); I^2 = 79%
Test for overall effect: Z = 1.33 (P = 0.18)

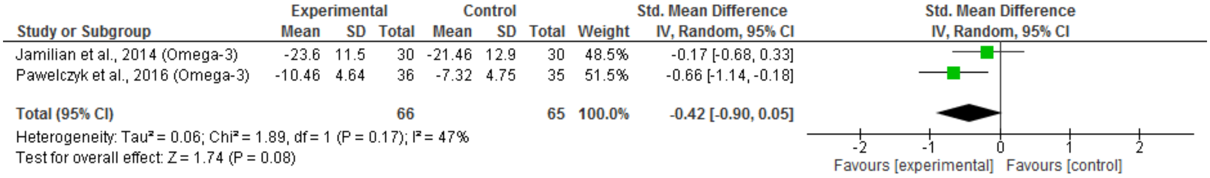
Figure 9: Variance in <u>Positive</u> symptoms of Psychosis from the meta-analysed data (n=2 studies) following intervention with Omega-3 fatty acids



	Experimental			Control				Mean Difference
Study or Subgroup	**Mean**	**SD**	**Total**	**Mean**	**SD**	**Total**	**Weight**	**IV, Random, 95% CI**
Pawelczyk et al., 2016 (Omega-3)	-2.12	2.58	36	-1.43	2.63	35	89.7%	-0.69 [-1.90, 0.52]
Jamilian et al., 2014 (Omega-3)	-11.7	7	30	-11.86	7.1	30	10.3%	0.16 [-3.41, 3.73]
Total (95% CI)			**66**			**65**	**100.0%**	**-0.60 [-1.75, 0.55]**

Heterogeneity: Tau^2 = 0.00; Chi^2 = 0.20, df = 1 (P = 0.66); I^2 = 0%
Test for overall effect: Z = 1.03 (P = 0.30)

Figure 10: Variance in <u>Negative</u> symptoms of Psychosis from the meta-analysed data (n=2 studies) following intervention with Omega-3 fatty acids



Study or Subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
Jamilian et al., 2014 (Omega-3)	-23.6	11.5	30	-21.46	12.9	30	48.5%	-0.17 [-0.68, 0.33]
Pawelczyk et al., 2016 (Omega-3)	-10.46	4.64	36	-7.32	4.75	35	51.5%	-0.66 [-1.14, -0.18]
Total (95% CI)			**66**			**65**	**100.0%**	**-0.42 [-0.90, 0.05]**

Heterogeneity: Tau² = 0.06; Chi² = 1.89, df = 1 (P = 0.17); I² = 47%
Test for overall effect: Z = 1.74 (P = 0.08)

Figure 11: Variance in General symptoms of Psychosis from the meta-analysed data (n=2 studies) following intervention with Omega-3 fatty acids

4.15.3 Vitamins

Two RCTs trialled the efficacy of vitamin C (n=1) (Dhakale et al., 2005) and vitamin D (n=1) (Krivoy et al., 2017) on the presence of psychotic symptoms, one study measured psychotic symptoms using the PANSS (Krivoy et al., 2017), and the other used the BPRS (Dhakale et al., 2005).

4.15.3.1 Vitamin C

One RCT of the efficacy of providing 500mg of vitamin C, versus placebo, to a sample of 40 participants (20 treatment:20 placebo) was reported, with all diagnosed with schizophrenia, as assessed by the BPRS (Dhakale et al., 2005). Analysis of between-group differences was conducted using the unpaired t test (Dhakale et al., 2005). The authors reported a significant improvement in psychotic symptoms in the treatment group compared to placebo, as defined by a significant (7.86, p<0.01) reduction in BPRS score above that of the placebo group (Dhakale et al., 2005).

4.15.3.2 Vitamin D

One study trialled the efficacy of vitamin D (14,000 IU) treatment for eight weeks, versus placebo in a sample of 47 adults with schizophrenia (n=24 treatment: 23 placebo) (Krivoy et al., 2017). The statistical analysis for treatment effect over time was conducted using the General Linear Model with Repeated Measures (Krivoy et al., 2017). The trial demonstrated no benefit in psychosis symptoms with a mean reduction in total PANSS scores of -8.9 +/- 7.3 for the treatment arm and -10 +/- 10.2 for the placebo arm (Z(45) = 0.45; p=0.65) that favoured the placebo arm (Krivoy et al., 2017). The mean change in scores for the PANSS positive (Z(45) = 0.53; p=0.59) and general (Z(45)=1.49; p=0.14) symptom subscales also displayed a trend that favoured placebo, with only negative (Z(45) = -0.83; p=0.41) symptom subscale favouring treatment (p=0.41); none were significant (Krivoy et al., 2017).

4.16 Discussion

4.16.1 Summary of evidence

This systematic review and meta-analyses aimed to ascertain the extent to which diet or dietary supplements improved psychosis symptoms in participants aged 14-65 years of age. There were nine included studies that spanned four continents, comprising participants drawn from both community and inpatient settings, which measured psychosis using the validated PANSS (n=7) and/or the BPRS (n=2). All included studies trialled the efficacy of nutrient dietary supplements as an adjunct to existing treatment and none trialled whole foods or wider dietary modification. Of the included studies, seven out of the nine reported an improvement in symptoms that favoured the treatment group, of which five reported a statistically significant improvement (See Table 4.6). Two reported an improvement that favoured placebo, of which neither were significant. Studies reporting a significant improvement in symptoms represented the nutrients lysine (n=2), vitamin C, taurine and omega-3 fatty acids. Nutrients not providing benefit were creatine, theanine and vitamin D. Four of the nine studies were pooled in two separate meta-analyses; one of which pooled the trials (n=2) of omega-3 fatty acids and the other pooled the trials (n=2) of lysine.

Of the nine studies included, only five studies reported a result that favoured treatment (Zeinoddini et al., 2014; O'Donnell et al., 2016; Jamilian et al., 2014; Pawelczyk et al., 2016; Dhakale et al., 2005), of which four were reported as significant (Zeinoddini et al., 2014; O'Donnell et al., 2016; Pawelczyk et al., 2016; Dhakale et al., 2005). Of the remaining four studies, one only reported psychosis subscale score data, but not total psychosis score data (Ritsner et al., 2011) and the other three favoured placebo (Kapstan et al., 2007; Wass et al., 2011 and Krivoy et al., 2017). Data from the pooled analysis of fatty acids (Pawelczyk et al., 2016; Jamilian et al., 2014) suggested a singnificantly beneficial effect favouring treatment over placebo. Data from the pooled analysis of Lysine (Wass et al., 2011 and Zeinoddini et al., 2014) did not represent a significant finding. All of the studies did not report on concurrent dietary habits or nutrient intake throughout the duration of the study (or at baseline), thus the true intake of treatment nutrients in both groups remains unknown, rendering all results subject to error. Based on this systematic review of the literature, none of these diet interventions can therefore be considered as having value for psychosis management.

4.16.2 Wider discussion

Despite the serious limitation presented by a lack of diet recording within the two omega-3 fatty acid studies, the significantly beneficial effect of omega-3 fatty acids on psychosis symptoms from this pooled meta-analysis is noteworthy because it resonates with a similar study aimed at preventing the development of psychosis symptoms in a cohort of high-psychosis risk adolescents and adults (Amminger et al., 2010). The RCT provided treatment participants with a daily dose of 4 capsules provided 700 mg of eicosapentaenoic acid (20:5 omega-3), 480 mg of docosahexaenoic acid (22:6 omega-3), and 7.6 mg of vitamin E (Amminger et al., 2010). The placebo group were provided with matched capsules containing coconut oil; chosen because it has no polyunsaturated fatty acids and does not impact on omega-3 fatty acid metabolism (Amminger et al., 2010). The trial was conducted for 12 weeks with participants (n=81) who had an ultra-high risk of developing psychosis, showed a significantly beneficial effect at preventing the onset of psychosis (22.6% between-group reduction in conversion rate; 95% CI: 4.4-40.4; p=0.007) at 12-months post-trial (Amminger, 2010). The beneficial outcome of that trial was still present as a significant reduction in rate of those developing psychosis within this cohort (30.2% reduced conversion in the treatment group; 95% CI: 10.1–50.4, with continuity correction) seven years post-intervention (Amminger, 2015).

The meta-analysis of lysine showed no statistical beneficial improvement to psychotic symptoms over placebo (Wass et al., 2011 and Zeinoddini et al., 2014). This finding may be explained firstly by the fact that the outcome of one study favoured treatment (Zeinoddini et al., 2014), whilst the other favoured placebo (Wass et al., 2011) and the high heterogeneity in this sample (I^2 = 98%) and furthermore by the relatively small cumulative sample size. Likewise, the result may have been impacted through dietary modification by participants, as this was not monitored throughout the studies. One of the two studies Zeinoddini et al. (2014) consistently favoured treatment and the other Wass et al. (2011) consistently favoured placebo. The difference in findings between the studies may also be related to study design and duration of trial period, as the study that favoured placebo (Wass et al., 2011) only trialled lysine for a 4-week period compared to eight weeks in the study that favoured treatment (Zeinoddini et al., 2014). Further trials designed with robust methodology may be warranted as both lysine trials (Wass et al., 2011 and Zeinoddini et al., 2014) only reported 10% attrition rates from the study implying that the supplement was well tolerated.

When interpreting the results of this systematic review, there were serious concerns evident with both the internal and external validity of studies. These include inadequate reporting on at least one of the bias domains for all of the nine included studies (internal validity), which then reduces the reliability and trustworthiness of the results presented. Likewise, the absence of dietary assessment and consequent reporting throughout the study period for all of the nine included studies reduces the validity of the results because the outcomes of providing these trialled supplements are predicated upon the provision of a set amount of a given nutrient. With a lack of measurement of diet, there is no clear measurement on the levels of trial nutrients being ingested during the study period, thus rendering the measured ‘effect’ over placebo inaccurate. The trials should have included a validated measure of dietary intake at baseline and throughout, such as a food frequency questionnaire or food diary, which can support a nutritional analysis using diet analysis software (Kowalkowska et al., 2013). It may then have been possible to account for factors, such as changes in dietary behaviour during the trial period. Individuals are different and act differently, therefore with no measure of their diet during the trial period, there is the potential that inter-individual variance in intake for trial nutrients may have significantly skewed the between-group differences reported. This raises questions about the accuracy and validity of both the findings from all individual studies and from the pooled analyses presented here.

In addition to the lack of clarity on the exact levels of trial nutrients consumed, due to a lack of diet recording, there were other issues that impacted on the generalisability of the results reported by the nine studies. One example is sufficient power within the RCT to detect the desired effect of the trialled agent (Valojerdi et al., 2017). Only four of the studies, one each for lysine (Zeinoddini et al., 2014), omega-3 fatty acids (Pawelczyk et al., 2016), vitamin D (Krivoy et al., 2017) and taurine (O’Donnell et al., 2016) reported sufficient detail suggesting that their sample sizes were justified and were sufficient to detect an effective measure of efficacy. Jamilian et al. (2016) reported a power calculation for their sample size, however their calculation was based upon a 4-point improvement in PANSS score for treatment over placebo. The authors do not give a clear rationale or justification for the clinical relevance of the use of this calculation as there is no accepted gold standard for interpreting the clinical significance of improvement in PANSS (Crosby et al., 2003; Hermes et al., 2012). This is a serious flaw potentially in the conduct and certainly in the reporting of these studies and must be considered in relation to the value placed on the findings.

There are some published accounts of the experiences of providing supplements to impact dietary change for those with a psychotic disorder (Fortino, 2015; Royal, 2015), It is unclear, however, across the studies included within this review what the authors considered a desired effect from the trialled agent and moreover whether that desired effect represented the views of the patients with schizophrenia or psychosis. This raises the additional issue of a lack of clarity on what constitutes a clinically significant improvement in psychosis symptoms for individuals, which is fundamental to the relevance of the outcomes of any RCT (Man-Son-Hing et al., 2002), including diet. The clinical significance of a treatment should be related to the concept of the Minimum Clinically Important Difference (MCID) in standardised instrument scores (Hermes et al., 2012), however this equates to the minimum difference in the score for the domain of interest that patients deem beneficial (Jaescheke et al., 1989).

Trialling dietary components is still an under-researched area as none of the included RCTs examined the effect of either wholefoods or a change to dietary habits on psychotic symptoms. Furthermore, there were only nine studies meeting this review's inclusion criteria that trialled the effect of dietary supplements on psychotic symptoms. The conduct of this review is set in the context of a PhD founded in Pragmatism and the value of the findings from the review and the meta-analysis must be considered therefore in relation to answering the review question and the PhD question. Taken at face value, the statistically significant findings for nutrients showing beneficial effects from the treatments as (taurine (n=1), lysine (n=2), vitamin C (n=1), and omega-3 fatty acids (n=1), see Table 4.6) provide examples of potential diet interventions that may support psychosis management. Trials designed around dietary supplements, however, are limited in that they may not represent a real-world dietary situation, or dietary behaviour in which these components of the diet interact (Lichtenstein and Russell, 2005; Peet, 2008; Marx et al., 2017). There is currently a paucity of RCTs evaluating the efficacy of diet or complex nutrient combinations, e.g. wholefoods, in the treatment of mental disorders (Marx et al., 2017). Additionally, supplemental nutrients taken orally do not individually meet our physiological requirements due to the interactions between different nutrients (Lichtenstein and Russell, 2005; Peet, 2008; Marx et al., 2017) and therefore study participants' diets are also very important and should be reported. Future research in this area is needed to incorporate the challenges that behaviour change would impose on the efficacy of dietary trials (Marx et al., 2017). Peet and Stokes (2005) recommended that healthcare practitioners consider the importance of providing nutritional and dietary advice, including the consumption of fish, in the holistic management of those with a psychotic disorder.

Peet (2008) considered that trials of individual nutrients were likely to give mixed results due to the complex way that nutrients interact with each other. One nutrient reviewed in this systematic review (theanine) provides an interesting and simple example which demonstrates how a simple combination of two or three foods provides a range of nutrients. The amino acid theanine is habitually consumed in the beverage tea (*Camelia sinensis*), however tea consumption would also be a natural source of caffeine for the body and would often when brewed be consumed with milk and sugar. Both milk and sugar contain fatty acids, amino acids, vitamins, minerals and glucose, for example, and thus are nutrient-rich foods in their own right. Both caffeine and sugar have been known to affect outcomes in mental health conditions (Lara, 2010) and therefore tea, a natural dietary source of theanine, is already subject to complex interactions on the physiology of the brain. This therefore indicates that the effect of any singular diet supplement will be subject to interaction from a range of nutrients consumed through the individual's habitual diet, highlighting the importance of diet recording and reporting as part of diet or diet supplement RCT studies.

The placebos used in trials can also themselves have nutritional properties, such as calcium-carbonate tablets which contain calcium. This is also true of certain medications. The impact of these placebos or medicines on the body has either not been acknowledged or addressed in the design of these trials nor it has not been reported. There is therefore the possibility that this has affected the outcomes and skewed all of the reported results within the systematic review. In addition to the effects of nutrient interactions, there is also the additional burden of known deficiencies from poor diets of those with psychosis (Henderson et al., 2006; Peet, 2008 and Williamson et al., 2015). These deficiencies include low omega-3 fatty acid, antioxidant vitamin (Peet, 2008 and Cao et al., 2016) and amino acid levels (Pataracchia, 2008). The implications of this, particularly in light of no reported dietary intake data, is that supplemental doses may have been insufficient in light of nutritional deficiency following long-term underconsumption of these nutrients.

In light of the issues noted with the included studies in terms of both internal and external validity, none of the included studies were of sufficient quality to be directly implemented within healthcare services for psychosis management. Nutritional research has long been scientifically driven and like many other fields of public health research has failed to consider the implementation and evaluation stages of interventional design (Becker and van Binsbergen, 2005 and Truswell, 2005). The majority of nutrition trial reports conclude with the need for more evidence, rather than considering the development and evaluation of diet-focussed healthcare interventions in line with the existing published evidence (Ioannidis, 2016). It seems logical therefore that further small-scale diet supplement trials and observational studies will not provide definitive solutions (Ioannidis, 2013; Ioannidis, 2016). There is a need for nutrition research to be designed in line with a clinically feasible health intervention, which ideally should be co-designed with patients, their families and with healthcare professionals (Andersson, 2017).

Linked to the concept of what equates a desired clinical effect for the intended recipients of an effective trialled agent, there is also the concept of what they deem acceptable. Some of the studies reported high attrition rates from their trials, with two representing drop out at a rate of between one quarter and one third (O'Donnell et al., 2016 and Ritsner et al., 2011). High attrition rates may indicate potential issues around the acceptability of the interventions, with issues including taste, palatability, or side effects. Whilst the reporting of attrition varied across the studies, none reported that they had sought the views of participants either prior to, during, or post, the intervention. The acceptability of a diet supplement intervention, which may reduce uptake or compliance may have a large impact on the generalisability of the findings, which should be explored through seeking the views of those with psychosis, as part of any future research on this topic.

Due to no whole food diet intervention studies being published, this review only examined studies that explored single nutrients or diet components, which does not replicate the naturalistic human diet. The investigation of the efficacy of individual nutrients or diet components has been labelled 'nutritionism' (Scrinis, 2008). The advantage of manipulating dietary components, such as these, is that RCTs can be conducted and replicated more easily than changing whole foods or food groups in the diet. The reasons are that it then becomes difficult to pinpoint what has influenced any resultant effects. The legitimacy of dissociating these relatively small dietary components from the wider diet and diet behaviours remains uncertain (Scrinis, 2008). Future research designs in this area should consider the need to avoid simply providing diet supplements as a long-term solution instead of supporting patients to change their diet (Staudacher et al., 2022). A recent qualitative study where patients with psychosis (n=10) were interviewed on their levels of autonomy and data analysed using qualitative content analysis reported that in general the patients sought more autonomy, with 67% indicating they had little choice over the care they received, despite believing themselves to be capable of participating in those decisions, even when acutely unwell (Haugom et al., 2022). Future research must therefore also acknowledge the views of patients and the difficulty that individuals experience when changing their diets (Marx et al., 2017). Peet and Stokes (2005) recommended that healthcare practitioners consider the importance of providing nutritional and dietary advice in line with international best practice and relevant public health messages, including the consumption of fish, (a rich source of omega-3) in the holistic management of psychotic disorders. Healthcare practitioners such as psychiatrists, mental health nurses, occupational therapists and dietitians working in clinical practice are ideally placed to provide more holistic support to patients with their diet (Peet and Stokes, 2005).

4.16.3 Implications of this review

The findings of this systematic review and meta-analyses indicate that whilst there were some diet supplements that demonstrated a beneficial effect following RCT, there were significant issues related to the quality of the included studies leading to low assurance of the internal and external validity of the findings provided. The findings of this review and meta-analyses are that none of the included studies represented a valid diet intervention that could be implemented in healthcare systems for psychosis management. Another issue with the included studies was that whilst studies presented a statistically significant result there was no clear rationale as to whether that represented a clinically significant results, as determined either by a gold standard measure of interpreting the outcome of psychosis rating scales, or based upon the views of those experiencing psychosis. The design of future trials of diet or diet supplements must address these fundamental design issues as the effect of dietary consumption on supplement dosage rates and psychiatric outcomes remains largely unknown.

The consumption of individual nutrients does not truly represent reality because nutrients are consumed in complex combinations through the diet. Peet (2008) also cites the importance of nutritional assessment and, where warranted, nutritional intervention, for those with psychosis. In line with other published work therefore, this systematic review, which included no studies on whole foods, also highlights the gap in the literature and the need to investigate the importance of considering diet as a whole and not of its component parts.

The principal recommendation from this review and meta-analyses would be to consider gaining an understanding of the clinical feasibility of this research through seeking the views of those experiencing psychosis. An exploration of key stakeholder views would support the development of a diet-related intervention for psychosis, which could be trialled for efficacy with a robust and appropriate methodological design.

4.17 Limitations of this review

A limitation is that the pooled sample size is low as both meta-analyses contained only two trials each with small sample sizes (see Table 4.3). The reporting of trial design was such that it is unclear whether dietary consumption of trial nutrients during the trial may have impacted on study outcomes. A further limitation in this review is the clear lack of any robust evidence of the effect of whole foods and the diet as opposed to trialling individual nutrients. Whilst it is acknowledged that this may be due to complex study designs, this is an essential part of understanding the true effect of nutrition on psychosis, i.e. in the context of the subjects' environment. This aligns to quantifying the value of pooled results from individual nutrients, as it is unclear a) whether the effect sizes reported on psychotic symptoms would change when these nutrients are given in complex packages, e.g. foodstuffs and b) how the effect of these nutrients could be practically applied as an intervention in a care setting.

A limitation of six of the included studies (Kapstan et al., 2007; Wass et al., 2011; Ritsner et al., 2011; Jamilian et al., 2014, Zeinoddini et al., 2014, O' Donnell et al., 2016) is that participants with known co-morbid substance misuse issues were excluded. This has implications for the generalisability of the findings within the trial population, because of the proportion of those with psychosis with co-morbid substance misuse (42%; Hunt et al., 2018). It is unclear to what extent substance misuse may have impacted on the physiology of those individuals and consequently their nutritional requirements. Future trials of diet or diet supplements should be more inclusive in their inclusion criteria to support a sample that is more representative of the population.

4.18 Conclusion

This review concludes that there are several nutrients that have shown improvement on psychotic symptoms versus placebo as an adjunct to usual treatment, with a pooled analysis of omega-3 fatty acids showing significant benefit at reducing psychosis symptoms, compared to placebo. There are, however, no studies that examine the effect of these nutrients in the context of foods or an individual's dietary behaviour. Consideration should be given to understanding the views of those with psychosis on the key components of a diet-related intervention, which form the basis of the subsequent chapters of this PhD thesis.

4.19 Lay Summary

A search was conducted to see whether any diet or diet supplements has been tested to see if they helped adults manage their psychosis. A total of nine studies were examined out of 32,070 possible studies that had been published. All of the nine studies were of diet supplements, which ranged between fatty acids, amino acids and vitamins. The main finding was that whilst some of the diet supplements were found to be beneficial, namely: lysine, taurine, vitamin c and omega-3 fatty acid, others were not: creatine, lysine, theanine, omega-3 fatty acid and vitamin d. There were also problems with the quality of the studies, often combined with a lack of detail on how they had been done. These issues with the processes used led to an overall conclusion that based on these studies there were no definite diet or diet supplement intervention that could be used to manage psychosis.

4.20 Post-PhD literature search – April 2023

The outcome of the systematic review informed the subsequent phases of the PhD, however as the review was conducted between 2017 and 2019, the researcher considered it prudent to conduct an updated database search using the search criteria, to source any studies since July 2019 that met the inclusion criteria. The outcome of this search was to appraise any studies and consider how their inclusion would have influenced a) the findings of the systematic review and then, if relevant, b) the subsequent direction of this PhD. Of the 983 citations, nine were reviewed as full text documents resulting in two that met the full inclusion criteria used in the conduct of this systematic review. Each of the studies is briefly summarised below and then a commentary on their impact on the systematic review and wider PhD follows.

4.20.1 Study 1 – Gaughran et al. (2021): "Effect of Vitamin D Supplementation on Outcomes in People With Early Psychosis: The DFEND Randomized Clinical Trial"

Trialling the efficacy of Vitamin D (120.000 IU at 20,000 units per month over 6 months) versus placebo on psychosis symptoms found a mean reduction in total symptoms (assessed via PANSS) favouring the placebo group, of 3.57, which was not significant (p=0.13; CI, −1.11 to 8.25).

4.20.2 Study 2 – Jamilian and Ghaderi (2021): "The Effects of Probiotic and Selenium Co-supplementation on Clinical and Metabolic Scales in Chronic Schizophrenia: a Randomized, Double-blind, Placebo-Controlled Trial"

Trialling the efficacy of daily selenium (200µg) and probiotics: Lactobacillus acidophilus, Bifidobacterium lactis, Bifidobacterium bifidum, and Bifidobacterium longum (8 x 10^9 colony forming units) for 12 weeks found the greater reduction -1.80 in total psychosis symptoms favouring the trial agent, assessed via the PANSS, was not significant (p=0.08; 95% CI, −3.85 to 0.23) (Jamilian and Ghaderi, 2021).

Potential Impact of these studies on the findings of this PhD

Neither of these two recent studies (Gaughran et al., 2021; Jamilian and Ghaderi, 2021) demonstrated a beneficial effect on psychosis symptoms from their trial agents and thus have no value as diet interventions for the management of psychosis. Both studies repeated issues noted in those included in the systematic review in that they were also flawed in either not recording dietary intake (Gaughran et al., 2021) or recording it and then not reporting the data and not reporting whether the dietary intake of trialled nutrients (e.g. selenium) was factored into statistical analyses (Jamilian and Ghaderi, 2021). This questions the validity of the results in both studies.

In summary, the two papers published since the conduct of the systematic review and meta-analyses that informed the subsequent part of this PhD would not have changed the findings of the systematic review and thus would not have altered any of the conduct or findings of this PhD.

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5. PRACTICAL METHODS

This chapter details the practical steps taken whilst conducting two qualitative research studies by which the views of the stakeholder cohorts were sought. These studies were non-sequential and were completed in parallel, as part of the explanatory sequential study design (see Figure 1, in Chapter 3). The chapter begins with the studies' research questions, aims and objectives and is followed by a description and justification of the recruitment strategy and expected sample, the regulatory approvals and the data collection and analysis approaches. There are dedicated sub-sections, where appropriate, to distinguish when there are differences in the research approach between the conduct of the HCP and the Patient and Carers studies.

5.1 Overview of the two qualitative studies – Research Questions, Aims and Objectives

For both qualitative studies the development of the research aims, objectives and the research questions were an iterative process that were developed and refined over time by the Lead Researcher, with support and discussion from the supervisory team and were aligned with the PhD's primary research question. This process was informed by the findings from the systematic review alongside prior knowledge and clinical experience.

Reflective Diary excerpt

Examples of the iterative changes that occurred included the refinement of research questions and objectives to improve clarity of meaning. For example, clarity was improved by replacing phrases like 'to what extent…' with more direct language, such as 'how do…'These changes were made following periods of self-reflection and following advice given by the supervisory team until a final version was produced and finalised for both studies.

5.1.1 Health Care Professionals

5.1.1.1 Research Questions

1) How do HCPs describe the role of diet/nutrition as influencing brain health for those experiencing psychosis?
2) What are the views and experiences of HCPs on the role of diet/nutrition in the management of psychosis?

5.1.1.2 Aim

To explore healthcare professionals' views about diet and nutrition linked to brain health and their view on its potential as an intervention for the treatment of psychosis.

5.1.1.3 Objectives

1. To collect qualitative data from a cohort of healthcare professionals who have provided care for those with psychosis by conducting a series of focus groups (n=3-5 focus groups, with an expected range of 20-30 participants)
2. To analyse the data collected using thematic analysis as outlined by Braun and Clarke (2006)
3. To report and discuss the results of the data analysis

5.1.2 Patients and Carers

5.1.2.1 Research Questions

1) How do Patients and Carers describe the role of diet/nutrition as influencing brain health for those experiencing psychosis?
2) What are the views and experiences of Patients and Carers on the role of diet/nutrition in the management of psychosis?

5.1.2.2 Aim

To gain a greater understanding of the views of patients and carers about diet and its link to brain health and the potential as an intervention for treatment component in the management of psychosis.

5.1.2.3 Objectives

1. To collect qualitative data through semi-structured interviews with patients who have been treated for psychosis and ‘carers’ (n=15-30 participants)
2. To analyse the data collected using thematic analysis as outlined by Braun and Clarke (2006)
3. To report and discuss the results of the data analysis

5.1.3 Synthesis of stakeholders’ views

Following the individual analysis of both study datasets, a further objective was to synthesise the findings from both stakeholder groups to report and discuss elements of programme theory related to a diet intervention for psychosis management. These elements will form the core components of a diet intervention for psychosis management. Data synthesis was completed using the triangulation protocol (Farmer et al., 2006) with the synthesised data presented within a pipeline logic model (Funnell and Rogers, 2011).

Following completion of the systematic review and meta-analyses, the results and recommendations for future research included the need for continued stakeholder involvement as part of the development of a dietary intervention for those with psychosis (see Chapter 4, Section 4.16.2 for an overview). Gaining an understanding of the experience and perspectives of key stakeholders is a critical component of the success of any complex intervention by the MRC, as cited within their Framework on the development of complex interventions (Skivington et al., 2021).

Following a methodological discussion with the supervisory team, a pragmatic decision to split the collection of data from the stakeholder groups into two distinct studies was taken due to the different data collection strategies to be employed and due to the different requirements around national approvals. Participants were divided into: firstly, those delivering an intervention, namely Healthcare Professionals (HCPs) and secondly those in receipt of an intervention, which includes both patients and members of their informal care network (‘carers’).

5.2 Definition of the study populations

5.2.1 Healthcare Professional (HCP)

A Healthcare Professional (HCP) was defined as an individual employed by the recruiting NHS Trust and, as part of their role, who provided direct care to patients who have experienced psychosis. The HCP cohort comprised registered health and social care professionals, including nurses, psychiatrists, social workers, psychologists, and non-registered health care assistants.

5.2.2 Patient or Carer

The definition of ‘patient’ for the purposes of this study is someone who has been in receipt of care and treatment for psychosis from an NHS service. A carer is someone identified as part of the informal care network of a patient that has experienced psychosis and who is not employed by the patient or any health provider to provide care to them. Examples of individuals defined as carers include family members, spouses/partners or friends that provide support related to the person’s psychosis.

5.3 Patient and Public Involvement and Engagement (PPIE)

The two qualitative studies conducted as part of this PhD seek to collect data representing the views of HCPs, patients and carers as key stakeholders associated with a diet intervention for psychosis management. As discussed in the theoretical methods chapter (Chapter 3, Section 3.9), stakeholder involvement is also important in providing assurance on the design of research studies and research study materials. For both the HCP and Patient and Carers studies, the draft protocols detailing the proposed study alongside draft versions of the participant information sheets (PIS) and consent forms alongside the focus group and interview topic guides were shared with a group of representative stakeholders to seek their views prior to finalisation. These stakeholders were sent these materials electronically on an individual basis and asked to provide comments and feedback on the proposed design and any potential issues or errors they noted. The Lead Researcher reviewed the comments received and made revisions he considered were appropriate to improve the study. Members of the Stakeholder Review group that were employed HCPs, were currently paid by the Trust to undertake clinical roles and had experience of working within mental health services (n=3). They also had current or prior experience of providing care to individuals who had experienced psychosis both in community and inpatient services. Study document review was conducted by these individuals within working hours and with their line managers' permission. Those with lived experience of being patients that volunteered for the Trust as Patient Research Ambassadors (PRAS) also reviewed the study materials. Individuals did not receive any specific incentive to review the study materials related to this PhD.

Recruitment of all individuals that supported PPIE stakeholder review for both studies was conducted by an email sent by the NHS Trust's Research Team to all appropriate HCPs who had registered with the Trust as PPIE volunteers and to all Patient Research Ambassadors. PPIE volunteers interested in taking part were invited to contact the Lead Researcher by email, who provided them with copies of the study documents. Recruitment of those who expressed an interest (n=3) was carried out by the research team to minimise any discomfort that may be experienced by individuals if they had declined to take part. PPIE participants were given a suggested timeframe of 2 weeks to review the materials and return feedback on their views. They were made aware that they could return their views by email or as written copies delivered back to the Trust's Research Team base.

5.3.1 Feedback from the Stakeholder Review groups

The feedback received from the stakeholders added value to the process because it suggested that the studies would add value to the knowledge base and were likely to be well received. It also gave practical suggestions that could help avoid confusion or improve engagement with potential participants, both of which could lead to an improved experience for those taking part and perhaps to better quality data (Hoddinott et al., 2018).

The feedback from consultation with the HCP PPIE reference group were as follows:

> *"clear, easy to read and understand and it sounds very interesting and timely"*

> *"I think these are good to go; I wouldn't suggest any changes"*
>
> *"There's a mix up with versions on the consent form, but otherwise I think it looks fine"*

Two PRAs expressed an interest in reviewing study documents and both provided comments as follows:

> *"The documents are comprehensive and very professionally prepared as one would expect. From a Service User's perspective I might wonder if you will be taking my medication off me then giving me a diet sheet and telling me to get on with it! So you might wish to allay some fear and anxiety and say to people you are only going to interview them. That reassurance would really help me."*
>
> *"This looks really good… and I would have loved to take part but sadly am ineligible. I think the Teams will help you find people; they're very good."*

The suggested change to version control on the HCP Consent form was amended and the form was redrafted accordingly. Likewise, the point about reassuring potential participants that this was a research study exploring the value of diet intervention for psychosis management and was not a replacement for medication was a helpful point that was incorporated into the face-to-face discussion of the study to all potential participants prior to them providing informed consent. The amended document set for both studies represented the final versions of the study materials that were submitted for the required approvals, such as sponsor approval and for consideration of an ethical review committee.

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5.4 Study Timelines

The timeline for key study milestones, including dates of approvals and recruitment are listed in Table 5.1, below.

Table 5.1: Timeline of key milestones for the two qualitative studies

Healthcare Professionals Study		**Patient and Carer Study**	
Milestone	**Date**	**Milestone**	**Date**
University of Leeds Research Ethics Committee approval	5 June 2019	National Research Ethics Committee favourable opinion granted	17 December 2019
Health Research Authority approval	17 October 2019	Health Research Authority approval	18 December 2019
Confirmation of Capacity and Capability issued by NHS Trust	6 November 2019	Confirmation of Capacity and Capability issued by NHS Trust	6 January 2020
Recruitment		**Recruitment**	
Group A	14 November 2019	Participants 1 - 4	17 January 2020 – 24 February 2020
Group B	19 November 2019	**All non-urgent public health studies paused due to Covid-19*	
Group C	17 December 2019	Participants 5 - 14	3 October 2020 – 16 October 2020
Group D	9 January 2020		
Group E	6 February 2020		
Transcription	February 2020	Transcription	February 2020 – December 2020
Data analysis	December 2020 – December 2021	Data analysis	February 2020 – December 2021
Data synthesis	January 2022 – August 2022		

5.5 Sample

For each of the two qualitative studies the sample was purposively recruited (see theoretical methods, see Chapter 3, Section 3.8) from within a medium-sized mental health and community NHS Trust in the North of England.

5.5.1 Health Care Professionals (HCPs)

The sample comprised individuals working within mental health services who are contracted and paid to provide psychosis care - healthcare professionals. These HCPs had a range of roles and disciplines, from both inpatient and community services, who had expressed an interest to take part. These HCPs were screened for eligibility to take part using the inclusion and exclusion criteria presented in Table 5.2 prior to participation:

Table 5.2: Inclusion and Exclusion criteria for potential healthcare professional participants

Inclusion	**Exclusion**
Have a contract of employment within the NHS Trust	Does not have a contract of employment within the NHS Trust, e.g. volunteer
Works currently, or previously, within secondary mental health services providing care to those aged between 18 and 65 who had experienced psychosis	Works as a member of staff but does not directly provide care to patients as part of their role, e.g. administrative staff

All potential HCP participants were screened for their eligibility to participate in terms of experience of providing psychosis care through details listed within their email signature or contact details and cross-referencing with the Trust employee database published on the intranet. Participating professionals would comprise both registered and non-registered professionals employed within the medium sized mental health NHS Trust in the north of England who hosted the research project. The aim was to conduct a series of three to five focus groups with a total intended sample of 20-30 participants.

5.5.2 Patients and Carers

The sample comprised patients and carers that were screened for eligibility to take part using the inclusion and exclusion criteria presented in Table 5.3, following an expression of interest. Participants were required to be aged 18 years or older, principally due to the potential conflict that participants under 18 years of age due to restriction relating to the need for parental assent, which may have influenced the quality of the data collected.

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Table 5.3: Inclusion and exclusion criteria for potential patient and carer participants

Inclusion	**Exclusion**
Be aged 18 years of age or over at the time of participation	Be aged 17 years and under at the time of study participation
Have previous or current experience of either i) receiving treatment from NHS Trust services for the symptoms of psychosis (‘patient’), or ii) providing informal unpaid care for someone who has been treated for the symptoms of psychosis by The NHS Trust (‘carer’)	Have experience of receipt of treatment or the provision of informal unpaid care prior to 3 years at the time of study participation
Considered by the researcher to have the capacity to provide informed consent* to participate in the study at the time of data collection	Be considered, by the researcher, as lacking the capacity to provide informed consent to participate at the time of data collection
Have sufficient command of the English language to read and understand the consent form in order to provide informed consent* to participate in the study.	Have insufficient command of the English language to read and understand the consent form in order to provide informed consent to participate in the study

*See Chapter 5, Section 5.9, for more information

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5.6 Governance and Approvals

5.6.1 Sponsoring organisation approval

As sponsor of this study, the University of Leeds reviewed all documents for both studies in line with their policies prior to awarding sponsorship approval. This process was required prior to any submission via the Integrated Research Application System (IRAS) for National approvals or to seek a favourable ethical opinion.

5.6.2 Health Research Authority (HRA) approval

As both studies were being conducted within the National Health Service (NHS), approval was also required from the Health Research Authority (HRA), whose role is to protect and support the interests of patients whilst participating in any health or social care research (Health Research Authority, 2023a). An electronic submission, which outlined study methodology, recruitment strategy and plans for data collection and analysis, was made via the IRAS for each study:

- The IRAS application for the HCP study (Ref: 261606) was drafted between March 2019 and August 2019, with a final version submitted 20 August 2019. HRA granted approval for this study was granted on 17 October 2019 (Appendix 6).
- The IRAS application for the Patient and Carers study (Ref: 265219) was drafted between June 2019 and November 2019 and submitted 22 November 2019 and HRA approval granted 18 December 2019.

For each study, the document pack submitted via IRAS, comprised the respective study protocol, which incorporates a data management plan, PIS, consent form and proof of sponsor indemnity. A distress protocol was also included as an appendix of the protocol for the patient and carer study.

5.6.3 Ethical review

There were two separate ethical review boards that considered the HCP and Patient and Carers studies, firstly the University of Leeds School of Healthcare's own Medical Ethics Review board and secondly that National Research Ethics Committee (NREC).

5.6.3.1 University Ethics Committee review

A study documentation pack, including protocol, which incorporated a data management plan, any distress protocol, or risk assessments for the NHS site and sponsor organisation (University of Leeds), where warranted, and copies of the consent form and PIS for each study was submitted for consideration by the University of Leeds, School of Healthcare's Research Ethics Committee. The HCP study was submitted in the first instance and was granted a favourable opinion subject to the submission of minor amendments, as requested in the conditional letter dated 5th June 2019 (See Appendix 7). The Patients and Carers study was submitted on 21 October 2019, with a conditional approval letter granted on 30th October 2019. Final approval from the University of Leeds (sponsor organisation) was granted on 6 November 2019 date following submission of the amended documents. This permission allowed the researcher to proceed to seek national research ethics approvals.

5.6.3.2 National Research Ethics Committee (NREC) review

The HCP study did not require National Research Ethics Committee (NREC) approval as studies that collect data from staff as part of their role are considered to pose no significant ethical issues and therefore do not require review (Health Research Authority, 2023b). The Patient and Carer study did require NREC as this was a research study collecting health-related data from patients and members of the public.

The application for consideration by the NREC was made as part of the same IRAS application that sought HRA approval. A decision was made by those reviewing the IRAS that the study met the criteria of warranting only a proportionate review as opposed to a full review. A proportionate review is granted for studies conducted without any interventional procedures and where there is a low potential risk of harm to the participants based on the nature of the study and the study methodology used (Health Research Authority, 2023b). Following review, the favourable ethical opinion was granted on 17 December 2019 (see Appendix 8). This study was conducted in compliance with the study protocol and University of Leeds regulatory and monitoring requirements.

5.6.4 NHS site approval

Research and Development (R and D) approval was required from the host NHS Trust as part of the HRA approvals process. The NHS Trust from which both samples were drawn required formal approval for the study to be granted firstly from the Trust's Governance Manager and then formally via their monthly Research Governance Panel. This is in line with their local research governance policy. The studies were approved at the panel meetings on 23 August 2019 (HCP study) and 22 November 2019 (Patients and Carers study). The Trust also provided written confirmation of its capacity and capability (CC&C) to undertake the research as agreed by the sponsor, the Health Research Authority and relevant research ethics committee(s) for both studies (see timeline presented in Table 5.1, Section 5.4).

5.7 Study Promotion

5.7.1 Health Care Professionals Study

Promotion of the study to potential participants was conducted between November 2019 and March 2020 by the Lead Researcher. To support a demographically diverse cohort attending the focus groups, the study was promoted to all professionals working within one NHS Trust in the North of England via several different routes.

5.7.1.1 Recruitment via electronic study promotion

An email promoting the study was circulated via the host NHS Trust's daily email communication bulletin which reaches all professionals and all services employed by the Trust. The same text was included in additional email messages sent directly to several Trust employed HCPs, including service managers, which were used to elicit opportunities to meet with potential participants to discuss the study face-to-face. The invitation asked that those interested in taking part should contact the Lead Researcher directly by email. Electronic copies of the Participant Information Sheet (PIS), consent form (see appendices 9 and 10) and the proposed dates, times and venues of the pre-planned focus group sessions were then provided to all interested potential participants. Potential participants were encouraged as part of this email exchange to ask any questions they had about taking part prior to attendance at a focus group session. Additionally, they were made aware that they could ask further questions with the lead researcher face-to-face prior to providing their consent to participate and prior to the start of data collection. Individuals who expressed an interest to participate were assigned to a focus group session at a date, time and location considered convenient for them.

5.7.1.2 Recruitment via face-to-face study promotion

Face-to-face attendance at relevant meetings (n=6) to promote the study was conducted between November 2019 and February 2020, which included attendance at the NHS Trust's three locality-based Care Group meetings. Additional face-to-face study promotion activity included informal discussion of the study with appropriate HCPs on an ad-hoc basis within this time period. The Trust had the following eligible services providing treatment for psychosis: eight community mental health teams (CMHT), three each of the early intervention in psychosis (EIP) services, the psychiatric intensive care units (PICU) n=3), and the inpatient-based rehabilitation units. Not all of the 17 eligible services agreed for the Lead Researcher to attend for reasons such as clinical pressures and staff sickness absence, but successful attendance at some of four of these services' meetings provided the opportunity to describe the study, answer any questions and distribute paper copies of the invitation to participate, Participant Information Sheet (PIS) and consent forms to potential participants.

5.7.2 Patients and Carers Study

All promotion of the study to potential participants to identify those that were interested to patriciate took place via one of the following two routes:

5.7.2.1 Via liaison with clinical services

The first route for the recruitment of patient and carer participants was by direct liaison with relevant clinical teams within the NHS Trust. An example of the invitation information is attached as Appendix 11. The lead researcher met face-to-face with HCPs in January and February 2020 at one of their weekly multi-disciplinary team (MDT) meetings. These were Early Intervention in Psychosis (EIP) teams (n=3), Community Mental Health teams (CMHT) (n=2) and Psychiatric Intensive Care Unit (PICU) teams (n=1), following receipt of a senior clinician's permission to attend these. The lead researcher presented the study orally providing key information about the study to the HCPs present at these meetings and asked if they could inform any colleagues of the study that were absent at the meeting. Following promotion at these multi-disciplinary team (MDT) meetings, HCPs were sent the information about the study and asked whether they would be willing to provide this information to the patients and to the family members of the patients that they had on their own caseloads. HCPs were asked to distribute the invitation to participate, which contained the contact details of the Lead Researcher thus allowing participants to make contact directly to express an interest in taking part.

HCPs from EIPS, PICU, CMHT and inpatient-based rehabilitation units across the three geographical localities of the Trust agreed to distribute study information to potential patient and carer participants. Patients and carers to whom the invitation to participate was distributed, were identified by HCPs who had firstly screened them for eligibility to take part using the study's inclusion and exclusion criteria. Following identification of potential participants, HCPs were asked to pass on a copy of the PIS (See Appendix 12) and the consent form (See Appendix 13), to those expressing an interest in participating.

5.7.2.2 Via direct access to potential participants through patient support groups and carer forums

The recruitment plan included attendance by the Lead Researcher at three NHS Trust's patient and carer support groups: The 'Listen to Learn' network, The 'Patient Research Ambassador' quarterly meeting, and The 'Carers Network'. These three meetings were scheduled to be held face-to-face. The plan was for the Lead Researcher to attend the meeting via a pre-booked slot on the agenda, and then distribute paper copies of the consent form and PIS to interested attendees. Due to the timing of recruitment however, the Listen to Learn and Carers Network meetings, were due to be held in March/April 2020 and were cancelled as a consequence of the Covid-19 pandemic. The Lead Researcher attended one Patient Research Ambassador (PRA) quarterly meeting (January 2020), which was a face-to-face meeting comprising patients and carers hosted by the Trust's Research Team. Those that expressed an interest in the study were provided with the Participant Information Sheet (PIS) and a copy of the consent form. It was during this meeting that they had the first opportunity to ask questions. Also, the offer was made to use the contact details to ask any subsequent questions, or those that individuals did not feel comfortable to ask within a group setting using the contact details listed in the PIS.

All interested individuals, irrespective of which route they were identified, who contacted the lead researcher expressing their interest to participate were sent copies of the PIS and consent form electronically and were offered the chance to have any questions answered. A mutually convenient date, time and location to meet face-to-face was then agreed by telephone discussion or via an email exchange for those willing to participate. All potential participants were given a minimum of 24 hours to consider whether they wished to participate following receipt of study information (PIS and consent form). This allowed them sufficient time to ask the researcher any remaining questions related to their participation in the study.

5.8 Recruitment Process

A potential participant was considered 'recruited' into either study at the point when they'd had all the study information presented to them, including what to expect during participation and what would happen to their data, and at a point when they had their questions sufficiently answered. This was documented through an initialled, signed and dated consent form completed in duplicate by the participant (initialled, signed and dated) and countersigned and dated by the Lead Researcher. One signed copy was returned to the participant for them to keep and the other was retained by the lead researcher and stored securely as per the study protocol. Participants were made aware, as part of the consent process, that they had the right to withdraw their participation at any point during the study up to the point at which data analysis had begun.

5.8.1 Delayed recruitment due to the Covid-19 Pandemic

Participant recruitment for the Patient and Carer study was planned between January 2020 and May 2020, however in March 2020 participant recruitment for this study had to be paused in line with a) the ban on face-to-face gatherings due to the Covid-19 pandemic and b) a local pause on student project data collection within the NHS Trust, in favour of conducting urgent public health research. The local NHS Trust continued to pause face-to-face gatherings and student study data collection until September 2020. The result of this led to a delay in recruitment of almost 6 months to the patient and carer study, with recruitment only ending October 2020, more than 5 months later than originally planned.

5.9 Consent to participate

The term informed consent requires three key elements: 1) that an individual or their nominated decision maker has the mental capacity to review the information and make a decision, 2) that a willing and voluntary decision is made to participate and 3) that the decision to participate is made following the presentation and review of all relevant information in relation to study participation (Shah et al., 2021). In line with the first of the five principles of the Mental Capacity Act (2005), capacity of individuals was assumed to be present. Due to the nature of psychosis, the mental capacity of potential participants was checked through the application of clinical judgement by the Lead Researcher who was conducting the interviews at the point of seeking informed consent. For the patient and carer study, an informal observation for any issues that may impede capacity, such as difficulties with concentration or memory retention (NICE, 2018), was conducted by the researcher prior to consent. None of the participants were regarded as lacking in the capacity to provide consent. If any issues had arisen, the process of consenting would have been stopped and participants thanked for their time. The process of providing informed consent for both studies occurred on a date and time pre-agreed by the Lead Researcher and the potential participant, which was following study promotion and interested individuals receiving an electronic copy of the PIS and consent form, for their review.

The informed consent process must be documented to provide a record. Consent was documented using a consent form prior to the start of each data collection interview or focus group, after individuals were invited to ask any further questions. The consent process was carried out by the lead researcher on a one-to-one basis for participants in interviews and focus groups. The consent form provided a written record of the individual's voluntary willingness to participate in all study-related procedures, including the sessions being audio-recorded prior to future transcription and that pseudonymised quotes from the session may be used in further publication. The consent form also contained information on a participant's rights regarding their withdrawal from the study, which for HCPs would not have affected their terms of employment within the recruiting NHS Trust and for patients and carers it would not have affected the care or treatment they received. All completed consent forms were scanned and stored temporarily on a secure NHS Server, which was only accessible by the Lead Researcher, in accordance with the data management plan approved within the study protocol.

5.9.1 Withdrawal of Consent

All participants in both studies were made aware via the PIS of their right to withdraw from the study at any point, without the need to give a reason (see Appendices 9 and 12). It was also made clear as part of these documents that any data collected up to point of withdrawal cannot be withdrawn and will be included as part of the analysis. No participants in either study withdrew their consent to participate.

5.10 Maintaining Confidentiality and Anonymity of participants

The processes for managing confidentiality and anonymity for the HCP and Patient and Carers studies is given below:

5.10.1 HCPs

Personal data collected from HCP participants included their name, signature, job role and professional qualification (if any), which was written by participants as part of the consent form (see Appendix 10). This was collected prior to the focus group commencing; it was collected from the individuals by the Lead Researcher and not shared with any other participating members of the group.

One of the limitations of group data collection is that participants cannot remain anonymous to each other during participation, however this was clearly explained to all individuals prior to participation and at the point where they were first made aware of the study. All participants therefore consented to participate in the full knowledge that they would be involved in a group discussion. Potential participants were made aware prior to commencement of data collection that they had the opportunity to withdraw from the focus group and that they did not need to give a reason for this.

Participants were asked not to state their name as part of the audio-recorded group session to prevent the identification of individuals within the subsequent transcripts produced from the session or any data extracts quoted as part of the reporting process. Each participant whose voice was audio-recorded during each of the five focus groups sessions was sequentially assigned a number starting with one based on order of first speaking within each session. This was prefixed with the letter R for respondent, so in a focus group session with eight participants, the first to speak would be recorded throughout the transcript as R1 and the last of the eight to speak would be recorded throughout as R8. Participants were therefore anonymous to the transcriber.

A master file was created, saved and held securely by the Lead Researcher on an NHS networked computer, logging for each focus group the corresponding name and professional role held by each of the respondents. This ensured full anonymity throughout the data analysis and dissemination process, as outlined to participant in the PIS and consent forms.

5.10.2 Patients and Carers

Personal data collected from patients and carers were limited to their contact details, which were either emails or phone numbers and home addresses where participants expressed that they wished to be seen at home. These were all held electronically by the Lead Researcher and were deleted at the end of the data collection period. The full names, signatures and details of whether a participant was considered a patient or carer was held securely on an NHS networked computer in an electronic master file. Patients and Carers were instructed not to say their name as part of the audio-recording and therefore remained anonymous throughout the process of transcribing. A pseudonym (first name only) was assigned to each participant for the purposes of data reporting, which allowed anonymity throughout the data analysis and dissemination processes.

5.11 Managing expectations regarding potential disclosure

In addition to protecting the identity of participants within both studies, it was also made clear as part of the consent process that the duty of care to protect the anonymity of individuals extended to any third party, such as patients, carers, colleagues or other members of the public. This duty also extended to the researcher's duty of care to report any potential safeguarding issues or malpractice. Participants may have been concerned about their anonymity and the confidentiality of the information they were willing to discuss within an interview, which may have adversely affected the data collected during the interviews. To mitigate this, information on data handling, data storage and data security were outlined in the PIS and consent form, both of which were provided to participants prior to interviews taking place.

With any research around healthcare there may be disclosures made that the research team have a duty to report. This was defined within guidance issued by the WHO

(2013a) because professionals have a duty of care to report certain disclosures and secondly there it the potential that research procedures could cause further damage to the individual. Or that if an incident has already occurred, intervention may reverse the effects (WHO, 2013a). This was regarded low risk during the proposed interviews and the lead researcher will escalate any such issues to his supervisory team as a matter of urgency. Details of this were covered in the PIS. In the event of an incident detailed contemporaneous notes would be made and would be stored securely in electronic format on the Lead Researcher's personal networked drive.

5.12 Potential for Participant Distress

It is very clear that no research participant should be subject to unnecessary distress, however there are instances when a participant may experience distress through their participation in research. Many people enjoy being interviewed, although there is also always a risk that people may become distressed when discussing personal experiences and therefore a distress protocol was developed for each of the studies. A process for handling distress was developed for each study, which outlined the proposed process for handling any such incidents, including immediate support following the distress and then signposting for any additional support both during and after participation, should it have become necessary. Sources of support were also outlined in the study's PIS. The lead researcher considered that the risk of a participant experiencing distress whilst participating in this study was low.

5.13 Risk Management

In addition to the distress protocol, a risk assessment was completed in line with the policies of the University of Leeds, in its capacity as Study Sponsor. The risks being assessed included the potential risk to those participating in the study and to the researcher. For both studies, the level of risk was scored as 'Low' for all categories and the risk assessment formed part of the submission which received a favourable opinion at the University of Leeds School of Healthcare's Research Ethics Committee.

Whilst the risk score was 'low', there was the potential for some risks to the researcher associated with the patient and carer study, which were the risks associated with lone working in the community. These risks were mitigated through completion of appropriate risk assessment forms such as University of Leeds' fieldwork risk assessment and lone worker risk assessment forms by the researcher and that the researcher has a clinical contract with the NHS Trust and therefore was up-to-date with related training.

The host Trust's Local Working Instruction for lone working as part of a research project was enacted as part of this research. In summary, the Local Working Instruction indicated that with prior agreement, a nominated member of either the clinical team associated with the care of the participant (either as patient or carer of a patient) or the research team (lead researcher's work base) was contacted immediately prior to each interview occurring at a potential participant's home. If they were not contacted within 1 hour of the expected completion of the interview, then these individuals were instructed to escalate this as a potential safety issue using the designated local (Trust) policy. Clinical team staff and research staff had access to all location details for interviews occurring within the homes of patients or carers.

5.14 Data collection

5.14.1 HCPs (Focus groups)

Data from the HCPs was collected via a series of focus group sessions (n=5) conducted between November 2019 and February 2020. Each focus group was conducted face-to-face and was audio recorded for intelligent verbatim transcription. Two focus groups were pre-planned generic sessions with dates sent to interested potential participants, and three focus groups were conducted pre-planned after Multi-Disciplinary Team (MDT) meetings or clinical handovers, following the service's pre-approval.

All focus groups were held within core office working hours between 9am and 5pm within NHS Trust buildings. These buildings were chosen for convenience and because they were familiar to staff and had sufficient car parking space, to minimise participant burden. To acknowledge that participants had given up their time to participate in the sessions, some light refreshments were provided at the sessions. The rooms in which the focus groups were held varied in size and shape, however tables and chairs were placed such that the group could form a circle, and all participants could see each other during the conversation. A check had also been made in advance of the session to ensure that there were no planned fire alarm tests or emergency procedures scheduled that could interrupt the data collection.

A topic guide was developed to guide the focus group discussions (see Appendix 14). The topics contained within the guide were developed by the researcher following the outcome and recommendations of the systematic review and meta-analysis as detailed previously in Chapter 4, Section 4.16. These were finalised following review by the Stakeholder reviewers, who suggested no changes to these following their review. The topics and prompts included knowledge on the topic of dietary links with mental health and views on what features a dietary intervention to support brain health should comprise.

5.14.2 Patient and Carers (Semi-structured interviews)

Data were collected from patients and carers through each participating in a single individual semi-structured interview between January 2020 and October 2020. The interviews were conducted using a pre-developed semi-structured interview topic guide (see Appendix 15), which provided sufficient structure and prompts to elicit data, but also allowed flexibility to respond with follow up questions based on the responses of the participant. The interviews, including the process of providing informed consent, were conducted at the location considered most convenient to the participant. All of the participants (n=14) elected to be interviewed whilst they were at home. Home visits were conducted in line with the University of Leeds Fieldwork Risk Assessment and the NHS Trust's local policies on lone working in relation to community visits.

Reflective diary excerpt

It was of note that some of the participants (n=4) chose to have a member of their clinical team present for the duration of the interview, although the member of the clinical team remained silent throughout the interview process. This was interesting firstly because it may have impacted on the participants' freedom or willingness to fully engage with the research. It was also interesting because that decision was relayed to the Lead Researcher by the HCPs in question that acted as chaperone throughout the interview, so it is difficult to fully explore the potential dynamic with regard to balance of power. Finally, it was interesting because these 4 interviews represented the 4 shortest interviews with participants.

The semi-structured interviews were audio recorded for the duration of the session from the point following completion of the informed consent process through until the end of the interview. The end of the interview was determined as the point at which the participant agreed that they had no more information they wished to give. Each audio file was downloaded by the lead researcher onto an encrypted NHS laptop and then stored securely on a secure NHS network. Each audio file was accessed by the lead researcher to produce a corresponding transcript of the interview session. These transcripts were the documents used for the purposes of data analysis. Interviews were all conducted by the Lead Researcher. Some of the interviews were relatively short in duration (16 minutes on average) and this was discussed with the supervisory team, (see reflective excerpt from the Researcher's research diary).

Reflective diary excerpt

"The duration of the interviews was something that I wasn't sure about and wanted to discuss in supervision. It felt, at the time of collection that some of the interviews were quite short in duration. I was worried that this may be wholly reflective of my technique. I discussed this in supervision and the advice given was to put participants at ease, make sure they are comfortable and explain ideas with example. This reassured me as that was what I was doing and then when I analysed the data and realised that a short duration could be expected, particularly as participants didn't have much knowledge on the topic, or much confidence in the knowledge they felt they did have. It is interesting in light of the reflection above that the interviews that concerned me at the time were shortest, were those where an HCP was present throughout. This would be something to consider for any future stakeholder engagement work related to the provision of diet intervention for psychosis management."

Following discussion with the supervisory team, a decision was made to include all of the interviews within the analysis even if the conversation was brief. This decision was made because all the participants actively participated in the interview process and provided answers, albeit brief, to all the questions asked.

5.15 Data Sufficiency

For the purposes of answering this PhD question, the rationale for accepting when sufficient data had been collected is outlined in the theoretical methods chapter (Chapter 3, Section 3.8.1). In practical terms, following the work of Guest et al. (2006), Guest et al. (2017) and Thomson (2010), sample size was determined as a minimum of two focus groups (HCP study) and a minimum of 10 individual interviews (Patient and Carer study). Additional focus group sessions and interviews were conducted following the researcher's view that data saturation had not been reached from these initial two focus group and 10 individual interviews. The researcher made their decision following their own assessment of the quality of the data with respect to how it answered the research question and then in conjunction with sharing and discussing interview transcripts at regular monthly supervision meetings. In total five focus group interviews were conducted (HCP study) and 14 individual interviews were conducted (Patient and Carers).

5.16 Data Transcription

5.16.1 HCPs Focus group data

In this study, primarily due to time constraints, the volume of the data and the known complexity of focus group discussion, which impacts on transcription time (Smithson, 2000), the researcher sought the services of a transcription service. This was a private company with which a confidentiality agreement existed between the company and The University of Leeds. The Lead Researcher submitted a direct request for transcription of audio files to the company and they responded by return asking for a list of specialist language, commonly used terms and any acronyms associated with the study to help them provide greater accuracy within the final transcripts. The Lead researcher provided a list of commonly used acronyms to the transcription service by email on 14 February 2020. The service completed transcription within 15 working days and uploaded the completed word files securely into the user account.

Following receipt of the transcript, a check was made against each audio file firstly for accuracy and secondly to determine whether any parts where voices overlapped could be clarified. Each of the five files were checked for typographical errors which were corrected by the researcher and the file was resaved with an updated version number. There were also incidences labelled as ‘missing text’, these referred to occurrences where the audio quality was too poor to allow accurate transcription. Any missing audio that the Lead Researcher could discern was corrected prior to any further review of the data. Once this was completed the transcripts were ready for analysis.

5.16.2 Patient and Carers

The Lead Researcher made the decision to transcribe the patient and carer data in order to become more familiar with the dataset. Transcription occurred between February 2020 and December 2020. Once complete, each transcript was checked by the lead researcher against the audio file for accuracy prior to analysis.

5.17 Data Management

In line with the study protocols’ data management plans, the focus group and individual interviews were audio recorded using a portable encrypted digital recording device. Study files containing scanned consent forms and the audio files were copied from the NHS server and uploaded at the earliest possible opportunity to the University of Leeds individual networked drive for secure storage. The audio files were deleted from the recording device immediately after the file was stored on the NHS server. Once safely stored on the University of Leeds server, the files were deleted from the NHS server. Prior to upload onto the University of Leeds server, all transcripts were checked thoroughly to ensure that they contained no information that would identify an individual. All paper copies of the signed, dated consent forms were stored as directed in the data management plans. In summary, these were stored in a locked metal filing cabinet within the NHS Trust's research team, located in a secure records room, which has both a yale lock and a numerical keypad. This room was located in a building with fob-level access, which was monitored closely by the building manager.

Storage of the transcripts and paper copies of the signed consent forms will be held for five years after the end of the study and then destroyed through deletion (electronic files) or by the NHS approved confidential waste disposal (paper consent forms) in line with their local destruction policy. The master document for each study was also stored securely on the University of Leeds server. These documents were retained for the duration of the study and will be deleted upon completion. All participant contact information was stored electronically on the NHS server and was deleted at the end of the study. All pseudonymised transcripts were copied onto the University of Leeds server and from there will be deposited into the Research Leeds Repository, upon completion of the final publication associated with this PhD, as detailed in the Data Management Plans. The Repository exists to allow other researchers to conduct a secondary analysis of this data in the future.

5.18 Data analysis

The data contained within the transcripts from both studies was analysed following the six-phase process of thematic analysis described by Braun and Clarke (2006). At the outset of the analytical process and prior to any data analysis, decisions were required regarding the approach the researcher would take to data handling. One of the decisions made prior to analysis was to take an inductive approach to coding the data based on the study-specific research questions (Braun and Clarke, 2006). The two study datasets 1) HCP focus groups and 2) patient and carer interviews, were analysed separately.

Alongside and throughout the process, detailed notes and reflections were logged in the Lead Researcher's research diary, which was completed in parallel to conducting the research. This was helpful as an aide-memoir, and it was helpful to provide detail when writing and discussing the results. This diary account of some of the practical steps being taken throughout the PhD, also provided the Lead Researcher the opportunity to reflect on the learning, knowledge and skills acquired throughout the process.

Reflective diary excerpt

"*I realised that I was struggling to see the themes and I needed a fresh perspective. In parallel to that I was asked to develop and deliver a presentation to 3rd year nursing students and as part of that I had to succinctly write my research into PowerPoint slides. This gave me the idea that I should try and summarise my themes using this programme to help highlight any themes that don't fit or are too cumbersome. It worked to an extent as it allowed me to see the ones that needed to be considered further.*

The example quoted from the diary was chosen because it displays some of the challenges associated with the PhD journey, such as struggles to define and name themes combined with a self-sourced practical solution.

5.18.1 Phase 1 – Familiarisation with the data

As suggested by Braun and Clarke (2006), the analytical process for each of these studies began with the reading of individual transcripts. This was done once prior to a second read-through which included any annotation to aid familiarity with the data. This was particularly important for the HPC focus group transcripts from the perspectives of familiarising the lead researcher with the data as the transcription for these was not completed by the lead researcher. Transcript annotation was completed electronically using the comments function within the track changes section of Microsoft Word. This was done for all transcripts prior to the initial coding phase. The process of data familiarisation described was completed between December 2019 and February 2020 for the HCP study and between February 2020 and December 2020 for the patients and carers study.

5.18.2 Phase 2 – Generating initial codes

To systematise and facilitate the process of coding, data handling was managed using NVivo (Version 12; QSR International Pty Ltd.), which is a software package specifically designed to allow researchers to organise large tracts of text, thus supporting the analytical process. To apply a code to the data using NVivo, the text was highlighted, ensuring there was sufficient text around the datum to maintain context. This was important as the presentation and discussion of data items without context is one of the criticisms levelled at thematic analysis (Braun and Clarke, 2006). Once highlighted, NVivo contains a function which allows the researcher either to assign a new code to the text, or to apply a previous code to the datum if this is a second incidence of the pattern. This process was completed for all data across the five HCP study transcripts between February 2020 and March 2020 and resulted in 916 initial codes and again for the Patient and Carer transcripts between March 2020 and January 2021 and resulted in 1235 initial codes.

Once the process of coding was completed, the data were exported from NVivo into Microsoft Excel and a sample of the codebook was share and discussed with PhD supervisors. The suggested and agreed first layer of refinement for the codes (total n=916 for the HCP study) following discussion at supervision was to re-read these and reconsider those which were not succinct, or those where the essence of the data actually required more refinement than the current code represented. An example of this was codes containing the conjunction 'but', which indicate that either there were multiple aspects of relevance to the given text, or it needed further abstraction to improve its meaning. A search and find was completed in the codebook using a specialist function in excel which highlights all incidences (N=44). The codes that seemed to be unclear were separated out and pasted into a separate excel spreadsheet (see Appendix 16 for a screenshot showing the generation of initial codes) to help the lead researcher sort and decide whether these codes were sufficiently clear and articulate in their current format, or whether they required amendment. The process was completed by cross-referencing the original datum in NVivo to ascertain the context of the datum to help inform the decision whether to split the code or re-articulate it.

Of the 'but' queries identified (n=44), four were errors through the use of the search function, such as the word 'contribute', however there were 23 that required rewording and there were 6 that required splitting into 2 separate codes, 13 that were removed and the text recoded to a different existing code. This resulted in a total of 911 codes remaining for the next phase of the analysis. A similar process occurred for the Patients and carers study codebook where the Lead Researcher checked for errors in the dataset and this resulted 23 errors, all of which were typographical and thus none of these codes required editing prior to further analysis.

5.18.3 Phase 3 – Searching for themes

A 'theme' is a descriptor that captures something from the data that is relevant to the research question (Braun and Clarke, 2006). According to Braun and Clarke (2006) the process of searching for themes is the process whereby the researcher re-focuses the analysis away from the individual codes to the broader themes that represent them. As described previously (see Section 5.18.2) the Lead Researcher chose Microsoft

Excel as the software program best suited to review the codebook and consider the themes. The ability to use multiple columns was helpful because it afforded columns to separate out codes relating to early versions of ‘themes’, such as ‘lack of knowledge’ (see Appendix 16), which was an important part of the early process of theme development. Additionally, the ability to insert or hide columns was also useful in viewing and sorting the large dataset to check for patterns and codes that may be linked together. In addition to the use of excel, the Lead Researcher concurrently accessed the NVivo software to cross-reference the code with the transcripts, which was helpful as part of the process to elucidate context or additional meaning from the original source text (Braun and Clarke, 2006).

The generation of themes was a process where the data was abstracted to find meaning that helped provide answers to the research question. Patterns within the abstracted findings were grouped together in themes. This analytical process required time and reflection by the lead researcher to avoid narrating a superficial description of the data. Throughout the analytical process, there were however, some data that had value at the level of description in answering the research question.

5.18.4 Phase 4 – Reviewing themes, Phase 5 – Defining and naming themes, Phase 6 – Producing the report

The remaining three phases that Braun and Clarke (2006) cite within their method of thematic analysis are phases 4, 5 and 6. These stages are conducted consecutively, however a key part of the process of analysis is to revisit and review the themes as part of honing them and defining their name. This was not finalised in the case of both the HCP and Patient and Carer studies until phase 6: the production of the report (the respective chapters within this PhD thesis). There were three main iterations of the reports (chapters) comprising the results and discussion of the thematic analysis, each of which had been reviewed by the supervisory team. Within each of these versions, there were multiple sub-edited versions.

To aid the defining and naming of the themes, a spider diagram was created (See Appendix 17) as a simple diagrammatic aid to consolidate the researcher’s view of the themes constructed from the data at a point in time. Note, the point of time chosen coincided with an annual PhD progress review conducted by a researcher from the University’s school of healthcare. The discussion was helpful from the Lead Researcher’s perspective as it forced the creation and development of the narrative required to describe the data within each of the themes, thus helping to consolidate the decisions around the value of the themes and how they were articulated. This links directly to the method described by Braun and Clarke (2006) as part of phase 5 of the analysis process, where they suggest that themes are to be challenged, refined or renamed prior to the completion of the report.

In terms of phase 6 and the production of the final report, which in the case of the two studies central to this PhD these, the ‘reports’ correspond to thesis chapters. The decision was made to aid the flow of each report to have one dedicated chapter for each study which detailed the results and their respective discussion points. These two chapters would be succeeded by a chapter describing the outcomes and discussion of the data produced following data synthesis across the two stakeholder groups.

5.19 Data synthesis

Following the Pragmatic approach to this PhD and as described in the theoretical methods chapter, (Chapter 3), the data from both studies were synthesised to add value in terms of answering the research question by providing a Logic Model that provides the core elements necessary for the development and consequent delivery of a diet intervention for psychosis management. Synthesis of the data from the two qualitative studies was conducted in line with the six steps outlined in the triangulation protocol (Farmer et al., 2006). The resultant outcome of the triangulation was not to produce a convergence matrix as suggested by Farmer et al. (2006), but to produce a logic model. Production of a Logic Model, as opposed to meta-themes, following integration of the findings was a more appropriate representation of the data in relation to the research question (see explanation in theoretical methods chapter, Chapter 3, Section 3.12). The Logic Model provided the core elements of a diet intervention for psychosis management from the two key stakeholder groups. The Logic Model articulates the key inputs, activities, outcomes and impact, alongside the key assumptions and external factors related to the diet intervention. A summary of the key tenets of the six steps, and a commentary of the practical actions taken to fulfil those, as part of this PhD are detailed in Table 5.4, below.

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Table 5.4: An explanation of the key phases of triangulation followed as part of the conduct of this PhD. (Source: Farmer et al., 2006)

Triangulation Phase	**Phase summary**	**Commentary within the conduct of this PhD**
1. Sorting	Sort findings from each data source or method into similarly categorized segments that address the research question(s) of interest to determine areas of content overlap and divergence.	This has been completed via: 1.Printing and manually annotating the findings from each of the two studies. An abstracted annotation, or meaningful statement that related each point to the research question was listed in the margin of each document. 2.Transcribing those statements collected from both of the studies into a single document, using separate coloured font for each of the two studies (green = HCP and blue = Patient and carer).
2. Convergence coding	Identify the themes from each data source. Compare the findings to determine the degree of convergence of (a) essence of the meaning and prominence of the themes presented and (b) provincial coverage and specific examples provided in relation to each theme. Characterize the degree and type of convergence using the following typifications of concurrence (or nonconcurrence) within theme areas. Convergence coding scheme <u>Agreement</u> There is full agreement between the sets of results on both elements of comparison (e.g., meaning and prominence are the same, provincial coverage and specific examples provided are the same). <u>Partial agreement</u> There is agreement on one but not both components (e.g., the meaning or prominence of themes is the same, provincial coverage or specific examples provided are the same). <u>Silence</u> One set of results covers the theme or example, whereas the other set of results is silent on the theme or example.	A pipeline logic model format was chosen (see Theoretical methods chapter; Chapter 3, Section 3.12.3) to present these codes and examine, through the narrative, areas of convergence, dissonance or silence. The convergence coding was completed as part of the process, with an example demonstrated in Appendix 18. Note the use of difference font colours to indicate areas of agreement, partial agreement and silence within the data. The coded segments were assimilated into one final logic model (final version, see synthesis chapter; Chapter 8, Figure 12) and key areas of agreement and silence are noted as part of the narrative, as appropriate.

Triangulation Phase	**Phase summary**	**Commentary within the conduct of this PhD**
	Dissonance There is disagreement between the sets of results on both elements of comparison (e.g., meaning and prominence are different; provincial coverage and specific examples provided are different).	
3. Convergence assessment	Review all compared segments to provide a global assessment of the level of convergence. Document when and where researchers have different perspectives on convergence or dissonance of findings.	Areas of convergence noted and discussed within the associated narrative with reference to its relation to answering the research question.
4. Completeness assessment	Compare the nature and scope of the unique topic areas for each data source or method to enhance the completeness of the united set of findings and identify key differences in scope and/or coverage.	Completed as part of the narrative, with particular reference to the content presented within the Logic Model.
5. Researcher comparison	Compare the assessments of convergence or dissonance and completeness of the united set of findings among multiple researchers to (a) clarify interpretations of the findings and (b) determine degree of agreement among researchers on triangulated findings. Plan for how disagreements will be handled and how final decisions on interpretations will be made.	The first draft of the logic model (see Appendix 18) and associated narrative was reviewed by the two PhD supervisors, who commented on major areas of agreement and disagreement*. *Note, because this was a PhD and represents an individual training project, this was done to a lesser extent
6. Feedback	Feedback of triangulated results to research team and/or stakeholders for review and clarification	Disseminated via the thesis and potentially post-PhD via oral presentation and peer-reviewed publication. One of the recommendations from this PhD, listed as a recommendation for future research (See Chapter 9), although with an expanded Stakeholder remit.

The staged process of data synthesis as outlined in Table 5.4 above, occurred between January 2022 and August 2022. Steps one to four were conducted between January 2022 and July 2022 and step 5 occurred between July 2022 and August 2022. Step 6, which included initial feedback is complete with the presentation and publication of this PhD thesis. The development of the logic model and associated narrative facilitated the development of a discussion on the synthesised data in relation to the research question and gave rise to a series of implications and areas for future research post-PhD (see Chapter 9). Study limitations associated with this PhD were also developed and discussed (see Chapter 9, Section 9.3), with a culmination of a conclusion section (see Chapter 9, Section 9.4).

5.20 Chapter Summary

This chapter has presented the practical methods used for the development and delivery of the two qualitative studies conducted as part of this PhD inquiry. Key areas described within this chapter include the development of the study protocol and associated documents, such as the PIS and consent form for each study. These were reviewed by appropriate stakeholders, with comments considered prior to being finalised. The chapter outlines the timescales for the conduct of these studies and includes details of the necessary approvals required. Likewise, within the chapter is detail on the strategies used for participant recruitment, data collection. data analysis for the individual studies and then the process of data synthesis. The following chapters (Chapter 6 and Chapter 7) present the results and discussion, respectively, for each of the two studies.

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6. RESULTS AND DISCUSSION OF HEALTHCARE PROFESSIONALS' VIEWS

This chapter presents and discusses the results of the study which sought the views of Healthcare Professionals (HCPs) on the topic of diet intervention for psychosis management. Following the lack of evidence for effective diet intervention and the lack of robust evidence for diet supplement intervention for psychosis following the systematic review of the literature, the aim of this study was to explore to what extent HCPs viewed diet as influencing brain health and to what extent they believed it had a role in supporting psychosis management. The chapter begins with an outline of the key characteristics of the sample and locations used for data collection and then provides a summary of the four constructed themes and a discussion for each. The results and discussion are presented together for each of the themes as discussed in Chapter 5, Section 5.18.4.

6.1 Study Sample

Tables 6.1 and 6.2, below, outlines key characteristics of the study sample which participated in the five focus group sessions.

Table 6.1: HCP study sample professional group characteristics

Professional discipline	**Group A**	**Group B**	**Group C**	**Group D**	**Group E**	**Total**
Nursing	1	1	4	3	6	15
Allied Health Professionals	1	1	1	2	0	5
Support Workers	0	1	2	1	0	4
Psychiatry	0	0	0	2	0	2
Total	**2**	**3**	**7**	**8**	**6**	**26**

As evident from Table 6.1, the five focus groups (n=5) comprised 26 participants in total (n=2;3;7;8;6) and spanned professional groups including nursing (n=15), psychiatry (n=2), allied health professions including psychology and social work (n=5) and support workers (n=4).

Table 6.2: HCP study sample psychosis service area characteristics

Service area	Group A	Group B	Group C	Group D	Group E	Total
Community services	1	3	7	8	0	19
Inpatient services	1	0	0	0	6	7
Total	**2**	**3**	**7**	**8**	**6**	**26**

As evident from Table 6.2, Health Care Professionals (HCPs) were recruited from adult inpatient (n=7) and community psychosis services (n=19), although most participants drew on wider previous experience in their discussion in the focus groups. The group sessions were conducted face-to-face in NHS buildings and were recorded and transcribed verbatim. Focus groups lasted between 15 and 37 minutes in duration, giving a total data time of 2 hrs 29 minutes for these interviews. There were no participants that withdrew their consent to participate either during or after a group session.

6.2 Overview of conceptualised HCP Themes

Four themes were constructed from the HCP focus group data. The first theme is focused on the need and desire for more knowledge on diet. The second theme focuses on HCPs views that their duty of care should extend to diet, whilst respecting a patient's right to choose and the third theme describes the HCP's perception of patient's dietary habits and the effect that having psychosis has on these habits. The fourth theme described factors to consider when developing and implementing diet-related support for psychosis, with features including content, accessibility and professional roles.

6.3 Theme 1: A desire for more knowledge on diet in relation to psychosis management

Within this theme, the data indicated that HCPs currently have a lack of knowledge in this topic, which raises their anxiety around the fear of providing misinformation to patients. They feel that they are well-placed as HCPs in mental health services to provide a diet intervention, and are supportive of the concept of it as a biopsychosocial model, but only after appropriate training and knowledge acquisition on their part. They clearly cited the need for adequate, accessible robust training opportunities, which span both pre-registration and post-registration should be made available prior to the commencement of a diet intervention for psychosis management.

HCPs welcomed and expressed a desire for more information on a diet intervention for psychosis management, which for some was because of a general interest in the topic (Group A), and others was due to a knowledge of nutritional deficiencies for those with psychosis.

> *"People [with psychosis] are often lacking in certain essential nutrients, like Omega-3s, vitamins and minerals, that can impact on symptoms of psychosis, particularly in early onset or people at risk of psychosis." (Group B)*

HCPs were also keen for diet intervention to support psychosis management and as a possible way to reduce the need for medication. This, they believed, would have the added benefit of improving the physical health of patients through reducing the risk of metabolic issues that result from the medication.

> *"So, if there are alternatives to try, to alleviate some symptoms, because some of the medications can be horrendous, can't they?… if there's something that can complement the medication then why not look at it." (Group A)*

Historically, psychiatrists have argued that, unlike other medical disciplines, mental health treatment did not fit neatly into the medical model and that much of the required care straddled psychological and social philosophies or approaches (Engel, 1977). Participants' conversations from one group (Group E) indicated that nutrition provides a good example of a biopsychosocial model that could be applied in the treatment for psychosis. HCPs value a holistic approach to care, one which demonstrates empathy and is central to the biopsychosocial model of treatment (Santos et al., 2018). Furthermore, participants believed that as part of a biopsychosocial approach, diet could provide patients with self-management strategies and a sense of empowerment. Furthermore, participants believed that as part of a biopsychosocial approach, providing patients with knowledge on diet could provide them with self-management strategies leading to a sense of empowerment.

> "*It would empower them by giving them something that they have control over and can do something about and that's not easy when you've got psychosis" (Group E)*

Participants were clear though that they had not received sufficient information on the topic as part of any professional training, with some participant stating that the one or two sessions they had on diet for mental health management related only to the physical support of patients with eating.

> *"I'm quite newly qualified… I have had about 1 day of lectures on the subject and then I did a couple of practicals and that's it. The practicals were just about eating and feeding people and not linked to their mental health at all, or it didn't feel that they were." (Group E)*

Additionally, some the sources of knowledge on the topic included private study (Group B) and receiving and passing on information gleaned from patients.

> *"Sometimes [I have sourced information via] dealing with other clients that have found certain things have helped." (Group C)*

An evidence-based approach to treatment is the delivery of care based on the best published evidence (Geddes et al., 1998). HCPs value an evidence-based practice approach to treatment and thus they acknowledged the weakness of relying on informal, anecdotal sources such as Google or information gleaned for patients (Group C). To that end they were willing to explore this topic further and would welcome diet intervention for psychosis training as part of their continuous professional development (Group D), although previous attempt to access this type of training failed because the course was discontinued.

> *"I put myself down for a course in nutrition, but there wasn't enough of an uptake so they've pulled the funding, about a year back. It was a personal thing to be able to pass onto patient, but it didn't materialise." (Group C)*

This view is corroborated by Vasiloglou et al. (2019), who considered that diet-related support, which they label as "nutrition counselling", is important for the care and treatment of those with chronic diseases, such as cancer and diabetes. They define this as a 2-way process between a patient and a healthcare professional through which a patient's nutritional goals and needs are evaluated, discussed and an action plan formulated (Vasiloglou et al. (2019). A recent systematic review of nurse-led dietary interventions for cancer patients and survivors included three studies published between 2005 and 2018 reported that whilst there are limited studies published in this topic, there was a positive trend toward improved dietary measures, such as fruit and vegetable intake (Gan et al., 2021). Vasiloglou et al. (2019) believe that training, education, and interpersonal relationships are the core of effective counselling and specifically they considered the care and treatment of those with diabetes and obesity, their findings could be extrapolated to those with psychosis. Consideration firstly therefore that HCPs in mental health settings may be well positioned to provide a diet intervention for psychosis management, following appropriate training, because they have a rapport with patients and that diet intervention could become a core part of the role of existing HCPs in mental health services because it fits with their holistic approach to psychosis care. This should be considered in the development of an HCP delivered diet intervention for those with psychosis.

A perceived lack of knowledge from participants across the groups indicated that whilst they were enthusiastic about a diet intervention to help with psychosis management and perhaps a reduction in the impact of medication for patients, HCPs would require further knowledge on the topic to provide a safe and effective intervention. The data suggested that HCPs had concerns about providing dietary support because of the potential to cause harm through providing patients with inadequate information as a result of their lack of knowledge (Group A) or worse to provide information that may be detrimental to their physical or mental health.

> *“If you’ve got people with diabetes or on other medications where their diet can make them be unwell, you don’t want to go into that territory and give the wrong advice, do you?” (Group D).*

The data also represented, at times, a lack of confidence and hesitation which may stem from the risk of causing harm to patients through providing misinformation due to a lack of appropriate knowledge, which they equate with professional negligence. Anxiety may also manifest between the perceived need to balance appropriate discussions whilst risking the therapeutic relationship and the balance of where to prioritise the implementation of a diet intervention with other strands of care.

> *“They almost need to deal with other things first, and you do keep revisiting it, but then it’s how often do you revisit it without actually sounding like a broken record and they’re just telling you to go away? Which obviously, again, isn’t helpful.” (Group A)*

These data indicate that for these participants, the value of the therapeutic relationship is key, however that requires a confident HCP who has sufficient knowledge. It may be the case that their unwillingness to challenge the therapeutic relationship stems from a lack of confidence in their own knowledge around diet as opposed to their inability to read their patient. It seems fair to assume that if the HCP doesn’t have confidence in their own knowledge, they may feel they are breaching a trust placed in them if they are suggesting someone should act on their advice. It is also possible that HCPs consider that diet is not an essential or important part of the care of someone with psychosis and thus not worthy of a discussion which may jeopardise their relationship with their patient. If HCPs had sufficient knowledge on the benefits that diet intervention could bring to psychosis management then they would feel more confident and able to raise this effectively with a patient. These data are indicating several key points that must be considered as part of the development and delivery of a diet intervention for psychosis. These include the importance of training the staff to give them the knowledge they need to provide a safe and effective intervention, thus minimising the risk of harm from misinformation. Appropriate training leading to knowledge acquisition of staff will also help aid their understanding of the topic and inspire confidence in them that this is worthwhile for patients. The knowledge and confidence in the topic will then reduce any anxieties they currently have around providing an intervention like this, including fears over damaging the therapeutic relationship. Prior to, or a key part of, the development of a diet intervention for psychosis is the need to include within a training course a component that ensures staff feel confident to deliver it.

There is a parallel to other similar discussions they would have aimed at improving a patient’s health. The Francis Report (2013) was published following an inquiry into findings at the Mid Staffordshire NHS Trust, which had occurred between 2005 and 2009. The key findings of this report included a lack of fundamental care for patients, such as a lack of support for patients around feeding and drinking (Francis, 2013). The overarching recommendation from the report was that all professionals and services must work to keep the patient at the centre of care delivery at all times (Francis, 2013). Another recommendation from this report was that professional learning should be a mandated responsibility for accountable officers within healthcare services and that nurses should have a learning portfolio that demonstrates care, compassion and commitment (Francis, 2013). It may be the case that with sufficient training and an improved access to up-to-date knowledge of diet in relation to psychosis management, the anxieties of HCP participants within this study may be reduced.

One datum cites an HCP questioning that they perceive themself to have a full knowledge of the prescribed psychotropic agents that they administer, but not a full rationale for why dietary supplements were prescribed to patients in their service (Group B). This gives the individual anxiety around their ability to provide safe and evidence-based care for patients. It is possible that this individual doesn't have sufficient knowledge of the prescribed agents, which is potentially negligible, indefensible behaviour on the part of the HCP, or it is possible that this is an example of mis-placed anxiety stemming from a lack of assurance that their knowledge is correct. It seems unlikely that a qualified HCP would be completely unaware of a prescribed agent that they are administering to patients in their care. It seems more likely to stem from a combination of the lack of assurance of their own knowledge and the confidence that would bring. HCPs are also aware though that they as are perceived as a trusted source of information and care through the NHS umbrella. This informs the development of a diet intervention for psychosis management because it suggests in addition to the need for HCP training allow them to safely, confidently and effectively deliver a diet intervention, there must also be a mechanism to monitor their knowledge acquisition to provide assurance both to services and to the HCPs themselves that they know enough to deliver this safely and effectively.

The data indicated that irrespective of the provision of adequate training and information available to these HCPs, there was still a debate as to who should be responsible for providing a diet intervention to patients. Some believed that a basic grasp of nutrition concepts in relation to psychosis management would be helpful to all HCPs, but diet and nutrition is a specialism and therefore responsibility for it should be held by someone who was an expert in the topic and has the time to do it appropriately.

> *"I think to a certain degree it would be good, but I think it would never replace having access to a nutritionist. So I think it's a good idea to have a basic level of knowledge built into sort of early training, that's great. But I think you would never be able to take on the same amount of knowledge and learning that a nutritionist would, where that's their main role of focus, that's what they do. Because I just think that would just be too big, because there's too much else that you have to do as well." (Group D)*

The development and implementation of a diet intervention for psychosis management must consider the skills and capacity required to deliver it within services. The role of the mental health nurse has broadened over the last few decades with many nurses expanding their roles and skills through qualifications in areas such as psychotherapy or prescribing (Hurley et al., 2022). In parallel to that, community-based nurses are often responsible for case management or care co-ordination (Hurley et al., 2022). The previous datum (Group D) is noteworthy because this HCP is suggesting that nurses are not best placed to advise on diet and nutrition. This is in contrast with the view that those who consider nurses are a part of the core team providing treatment and thus are best placed to have dietary support as a part of their role (Vasiloglou et al., 2019).

Data from this study agree with examples from published evidence that some mental health professionals are keen to maintain a professional identity synonymous with their own registration and qualification, however the nature of that identity isn't always clear (Crawford et al., 2008). Happell (2014) considers 'identity' to be a key part of being a professional and details a debate where in many countries the nursing curricula is lacking in specialist knowledge of mental health conditions, such as psychosis and that mental health nursing should be taught as a specialism by those with appropriate experience and qualifications. It is interesting to reflect on the extent by which these values correlate with the tenets of their professional codes of conduct and what role nutrition education could play in a mental health nursing curriculum. Participants suggested that irrespective of which professionals should deliver a diet intervention, the concept of diet intervention for psychosis management should be incorporated as part of dietetic, nutritionist, nursing and other HCP curricula (Group D). One participant was actively discouraged from considering diet as an appropriate assignment subject as part of their nursing degree.

> *"I was told it wasn't particularly a very nursey subject to be looking at."*
> *(Group B)*

A lack of robust formal education opportunities for HCPs who would like to support patients with their diets is worthy of note as HCPs should be offered the choice to provide formal diet support. This is worthy of further consideration in relation to any future development phases of a dietary intervention for those with psychosis. One explanation for a lack of provision to date includes the limitations imposed by the professional bodies or the willingness or otherwise of higher education institutions to change or modify their pre-registration syllabuses. This warrants exploration to underpin and assure the quality by which the diet intervention for psychosis is delivered.

The nature or type of training or learning opportunity is important and worthy of consideration prior to the development of a diet intervention to ensure it is effective and meets the needs of HCPs. This is supported in the findings of a recent meta-synthesis of nurses' views of the value of accessing post-registration learning, where CPD was considered fundamental to professionalism and to raising the standard of patient care (Mlambo et al., 2021). The extent to which post-registration learning or continuous professional development (CPD), becomes embedded in practice has been reviewed as part of an evaluation of the efficacy of a professional regulatory body's audit process (Illing et al., 2016). Part of the evaluation was a systematic review of the literature, which identified one theme that considered that preference varied by profession in terms of learning methods (Illing et al., 2016). Gould et al. (2007) surveyed 451 nurses (n=451) for their views on learning preference and concluded that work-based learning was most effective, whereas class-based learning was too far removed from practice. Another important finding from the review by Illing et al. (2016) was that HCPs may not accurately be able to ascertain their own competence and may not choose appropriate or relevant learning opportunities. One of the barriers to successful implementation of new knowledge post-CPD, was professionals' own self-doubt (Bucci et al. 2016). One finding from a more recent review into the effectiveness of CPD in nursing reported that the most efficacious CPD opportunities are those chosen by the individual nurses themselves (Robertson et al. 2020). Based on the data presented and discussed in this theme, it is unlikely that mental health nurses or other HCPs would currently opt for diet-related training because they aren't fully aware of the topic or the potential benefits it may bring to patients. An increased awareness early on in the development of a diet intervention for psychosis management is therefore warranted.

In order for CPD to be used effectively by professionals however, a culture that supports professional development must be part of the organisation's value systems (Robertson et al., 2020). Organisations must support HCPs firstly to access appropriate CPD and then they must allow and facilitate that to be implemented in practice (Mathers et al., 2012). Embedding CPD activities in the workplace results in beneficial changes for HCPs in terms of satisfaction at work and quality of care they provide (Robertson et al., 2020). A parallel example of CPD for HCPs is training on, and subsequent implementation of, family-based interventions for those with psychosis. A Cochrane review of RCT or quasi-RCT studies investigating efficacy of family interventions versus care as usual (n=53) reported that these could reduce relapse rates, hospital admissions and medication compliance (Pharaoh et al., 2010). The authors acknowledged though that the included studies suffered from a lack of methodological rigour (Pharaoh et al., 2010). Whilst family interventions have been trialled in many settings, one of the limiting factors is that there are published incidences of poorly implemented examples where a lack of training and a lack of post-training supervision were highlighted as barriers to implementation (Bucci et al., 2016).

The examples of family interventions from the literature resonate with the data presented here from this study relating to a dietary intervention for psychosis. A review of studies (n=43) reporting the use of family-based therapy also concluded that one of the factors influencing the success of implementation was a whole-team approach supported by a positive organisational culture (Eassom et al., 2014). These suggest that the over-arching barrier to the implementation of interventions like these is a lack of organisational support. The implementation of interventions within services has been the focus of research and three key domains were identified following a systematic review of the relevant literature (n=43 studies), which were: system, staff and intervention (Geerligs et al., 2018). It may be the case that training or knowledge is important for individuals, but it is at an organisational, or national level that these are important to consider as part of the development and implementation of a diet-related intervention for psychosis.

The data within this theme articulates the views that NHS mental health services are positive on the potential value of a diet intervention for psychosis management and they consider services should be open to providing a diet intervention as part of psychosis management and are well placed to do so. They feel therefore that a diet intervention should be an embedded part of psychosis care and should be delivered by HCPs working in mental health services. This they deem an example of a biopsychosocial model that fits with their values and could then form a core part of their role and they feel it could help patients, including with medication side effects. This helps answer the research question at the centre of this PhD by demonstrating that HCPs believe that mental health services should consider providing a diet intervention for psychosis management if there is sufficient evidence to warrant it. There is a current lack of sound knowledge on the topics amongst HCPs, and some have tried to access training, but the course was discontinued. They believe therefore that certainly prior to the roll-out of a diet intervention for psychosis management, robust training would be needed for HCPs. Evaluation of any training would be needed to understand the extent to which it leads to knowledge acquisition in staff, reassures staff in their ability and reduce their anxiety around the risk posed to patients through them providing misinformation. A mechanism is needed, supported by NHS Trusts and commissioners, going forward to ensure that robust training is available to HCPs in a rolling programme aligned to the delivery of a diet intervention for psychosis management.

6.4 Theme 2: Balancing duty of care around diet within services

As evident in Theme 1, HCPs support the concept that diet could impact on psychosis. Data within Theme 2 indicate that HCPs acknowledged that diet should be considered as part of their professional duty of care. Participants' conversations in the focus groups imply that whilst they have a duty around diet intervention, which isn't robustly articulated in current policies or within NHS service provision. A lack of instruction to HCPs means that they find it harder to decide how and when to manage diet-related choices for patients. Furthermore, they consider that any knowledge they have on diet in relation to health should be subject to the same candour as medication or other treatments provided. Participants also talk about, the need for balance between upholding a duty of care and the implications of restricting patients' freedom of choice by taking steps to manage their diet, such as when inpatient services provide patients with their food options. They find that a decision which limits a patient's right to choose in relation to diet, is particularly challenging with patients who are lacking in or have transient capacity or who have no choice as they are detained on an inpatient unit. Decisions taken to restrict or mandate other interventions, such as provision of medication to a patient lacking in capacity though, are made more easily and regularly. This may be because medical interventions are evidence-based and supported by policies.

The data indicated that services had a duty to provide patients with the best possible care. Phrases from the data included the word 'standards', which participants suggested should be upheld. The data also referenced health assessments, with some aspects being cited as lacking sufficient depth, or only there to 'tick a box'. This was a source of frustration for HCPs.

> *"Well, we have certain standards that we have to meet in early interventions… the physical health checks, and part of that is asking them if they do want any professional help with diet… but you just have that one tiny little box that asks you two questions about lifestyle, you know, the diet and exercise… it might only be mentioned once a year." (Group A)*

One participant voiced that there isn't currently a clear need from services or commissioners to discuss diet with patients, apart from a brief question at the annual physical health check. HCPs relay specific frustration that the annual check isn't robust in how it evaluates dietary needs and that due to the wording of the section on diet, they feel that patients don't tend to engage with it.

> *"A lot of them just, kind of, brush it off and go, yeah, like, meat and two veg. So actually, we could do with expanding on it, and maybe having a formal way of gathering that information and looking at diet." (Group C)*

HCPs thought services and thus HCPs and the agents of the service, had a duty to help correct known nutritional deficiencies, such as through supplementation, to patients under their care. Phrases from the data, such as ‘maybe advising everyone’ (Group D) and ‘essential nutrients’ (Group D), imply that supplementation to correct deficiencies would benefit all health, but whether that related to physical or mental health remains unclear (Group E). HCPs also recognised that supplementation must be done safely, in line with patients’ wishes, and that diet supplementation can do harm if mismanaged and that there may be organisational factors that preclude its usage*.*

> *“It doesn’t happen as much now because I think with the change in medics and then the cost element, I think it was often an issue when people had been discharged from the service and then they wouldn’t be able to have it continue to be prescribed.” (Group B)*

Examples from the data (Group A; Group B) are noteworthy because they show the difficult position that HCPs are currently facing in that they believe diet is important for patients both in terms of physical and mental health, yet this isn’t covered by service provision.

> “*it’s [diet] very important, but the whole physical health agenda has moved forward a lot over recent years, but I think if we’re not careful, we can actually forget that it’s also about the impact on mental health as well.” (Group B)*

The Health and Care Professions Council (HCPC) that registers allied health professions, such as occupational therapy and dietetics, has a statement that advocates reasonable steps to safeguard the mental wellbeing of patients:

> *“…must encourage and help service users, where appropriate, to maintain their own health and well-being, and support them so they can make informed decisions”* (HCPC, 2016; Standards of Conduct, Performance and Ethics, p. 5).

The statement from the HCPC is generic and doesn’t cite nutrition or diet specifically, but there is a clear link that diet could be an example of where HCPs should support patients to look after their own health and wellbeing. The Nursing and Midwifery Council (NMC) regulates the conduct of nurses in practice, has similar statements within their standards for nurses that indicate clear areas where diet should be considered as part of care. Examples include:

> *"…make sure you deliver the fundamentals of care effectively"* (NMC, 2018; Standards of Proficiency for Registered Nurses, p.6)

And

> *"…identify and use all appropriate opportunities, making reasonable adjustments when required, to discuss the impact of smoking, substance and alcohol use, sexual behaviours, diet and exercise on mental, physical and behavioural health and wellbeing, in the context of people's individual circumstances*" (NMC, 2018; Standards of Proficiency for Registered Nurses, p. 7).

It is interesting to note that the NMC considers dietary needs in the context of individuals' circumstances. This suggests that consideration of diet goes beyond mere food provision in inpatient settings and covers dietary discussion with patients who are being cared for in the community. A dietary intervention for psychosis management should then consider individualised support of patients, particularly as part of the care of those residing in the community.

It may be fundamental to the values held by the participants in this study that they believe they could not adequately provide diet-related support to patients with psychosis even if they could receive formal training, as they believe this to be a specialist role (Group D). HCPs reflected that whilst it ties in with the professional values set out in their codes of conduct (NMC, 2018; HCPC, 2018), there is no organisational or policy mandate within services currently for them to push this agenda with patients. Patients therefore may lack the knowledge that diet is an important consideration for their psychosis and therefore they are not making an informed choice when they brush off dietary discussions during the physical health check. Likewise, it was noted (Group B) that medical professionals are not discussing diet as part of their patient reviews, which may indicate a lack of expertise in the field of psychiatry. HCPs attributed the lack of impetus around dietary discussion in mental health to a longstanding disparity in service provision between mental health and physical health. Furthermore, they suggest that the focus of any dietary discussions within mental health is always on the link between diet and physical health, rather than any direct link to mental health. They believe that physical health has always had more prominence over mental health throughout history. This knowledge suggests that not all HCPs are the same or have the same influence over the provision of services, suggesting that for a diet intervention to be successfully embedded it requires organisational buy in, including the medical staff who will act as Responsible Medical Officers (RMOs) as suggested by the New Ways of Working for Psychiatrists report (Department of Health, 2005a) (see Chapter 2, Section 2.14).

Despite the current perception amongst these participants of a lack of policy on this topic, there are published examples that have explored this, which are described in the Background chapter of this thesis (see Chapter 2, Section 2.14). Another more generic white paper published by the Department of Health (2004) entitled: ‘Choosing health: making healthy choices easier’, reported following public consultation that people were keen to make healthier, but they couldn’t change alone and needed system-wide support from the Government to do so (Department of Health, 2004). The government acknowledged this finding and suggested that the NHS and retailers should work together to support healthier choices (Department of Health, 2004). Key parts of this paper included a drive to reduce obesity through healthier food choices and to improve mental health of the nation (Department of Health, 2004), however these two facets were not clearly combined thereby failing to connect policy to the importance of diet for mental health. Despite these reports and publications, HCPs either remain largely unaware of their existence or they perceive that little progress has been made towards these goals in mental health services in comparison to physical health care.

The World Health Assembly published and agreed an action plan in 2013, which sought to improve health planning for mental disorders across its 194 member states (WHO, 2013b). One of the plan’s four objectives, included the desire to provide comprehensive, responsive, and integrated mental health services and asked that governments and health ministers adapted to best meet the needs of their populations (WHO, 2013b). This plan was recently updated to reflect new knowledge and additional targets including an increased voice from stakeholders. Policy makers should develop strategies that incorporate the will of the people and that those in receipt of mental health services should be part of the inspectorate (Thornicroft et al., 2021). Thornicroft et al. (2021) would like to see improvements in mental health care policy and it seems reasonable to consider dietary care for psychosis an example of this. The findings of this study suggest that there is a need to engage with policy makers and service commissioners as a stakeholder group required for the development of a diet intervention for psychosis management.

HCPs believed that whilst dietary support for psychosis management was not mandated as a defined strand of care delivery across all services currently, service providers did have diet-related responsibilities. These include ensuring that the food provided on inpatient wards meets the patients' health needs (Group D) and is consistent with the messages that HCPs are working hard to promote.

> *"I notice up on the ward, and for as much as pudding and custard is lovely, it's sort of the staple pudding that's served for most meals. And I think if we're trying to educate them into what the diet can help and support with the symptoms, then maybe that should start in the hospitals so that we're providing them." (Group B)*

Likewise, participants suggested that services could do more to support healthy eating and diet skills (Group B) and they vented that some practical skills sessions for ward-based patients aren't in line with healthy eating standards.

> "*And a lot of the cooking they do is buns and baking and cakes But I guess, you know, it's just increasing some kind of skill, isn't it? [sarcastic laugh]." (Group D)*

These data are interesting because as HCPs with the responsibility to manage the care of an individual, they felt that they had no power to effect which foods are provided on the wards or are frustrated that HCPs in other services are not supporting patients' needs effectively. This potentially demonstrates that they don't feel they can challenge this within the organisation, which does have that power and mandate. This was something they believed to be important in relation to their professional values and their desire to ensure sound patient care is provided within the NHS. It may also link though to the concept of a desire to hold professional control over patients in a paternalistic sense. For these HCPs, healthy food options should be the obvious choice that healthcare services provide to those in their care. These data help answer the research question at the centre of this study because they firstly imply that a diet intervention is important for psychosis management, but some of the responsibility to provide it sits with NHS hospitals, not just the patients themselves. A change in service provision to make options healthier, which may form part of the initiation of a diet intervention as part of psychosis management, would require high-level buy in at an organisational level, or even at a national level. These views from HCPs that services, such as adult mental health impatient services, don't always provide satisfactory food and nutrition to patients is also noteworthy because it arguably goes against the NHS constitution, however they acknowledge that those are the preferred option of patients. Part of the NHS Constitution, which relates to the quality of care that patients have the right to receive, states that NHS services should provide food and nutrition suitable to sustain health and wellbeing, as follows:

> *"You have the right to receive suitable and nutritious food and hydration to sustain good health and wellbeing"* (Department of Health and Social Care, 2021).

The data inherent to this theme indicate that the highly processed foods described in the examples are high in sugar and fat, e.g. "*pudding and custard*" (Group B), are that these are not suitable foods that would "sustain good health and wellbeing" (DHSC, 2021) for patients with psychosis. Not least because some of these patients may not be at liberty to choose to eat elsewhere due to the issue of capacity or the tenets of the Mental Health Act 1983. These foods also go against NHS England's Care Quality Indicator (CQuIN) mandating a reduced provision of foods containing sugar, fat and/or salt and a desire to ban the promotion of such foods to patients (NHS England, 2017). The push from NHS England (NHSE) to support access to healthier food options implies that they see the value in nutritious food to support health, so it may be the case that they (NHSE) would be supportive of embedding diet intervention of psychosis management within the NHS.

Data in this theme indicate that HCPs believe the choices made by patients, e.g. on the ward or the community, are not always in their own best interests. These choices are however noted by participants to be within the spectrum of normal dietary habits in a U.K. population. The majority of participants acknowledged that there may be some mitigating reasons why patients engage in these less-than-optimal dietary behaviours, but that that they shouldn't lose sight of the importance of respecting a patient's right to choose when it comes to food. Some participants also debated that a part of their professional role was a duty to act as advocates for the wellbeing of patients on the wards, which they considered extended to diet, through supporting healthy choices and portion control (Group B). Participants also relayed experiences whereby patients have reflected post-discharge on a sadness at the weight they gained whilst residing on a ward at a time when they didn't have capacity to make informed decisions related to what they ate.

> *"I think some people have said when they've come out, and maybe at that time, like you say, it's not important to them. They come out, and then by the time I see them they're like, oh I can't believe that I've put on this much weight. But it's because they've been on the ward for however long and they've got into that routine." (Group B)*

Likewise, a participant relayed a struggle with defining the professional boundary with patients who had been advised on healthier options but had then refused to make healthier choices when these were provided for them on the ward (Group B). HCPs relayed a sense of frustration when patients are unable to make suggested changes to their diet, particularly when they were at home living in the community.

> *"It could be something like diet say and they wouldn't make the changes and I know it's understandable, but it was really frustrating… I think the frustration wasn't with them it was that I couldn't help them more really… You have to just accept it though and keep doing your job, it's all you can do. You just revisit it periodically and hope that they're then ready." (Group E)*

These data examples span both inpatient and community settings with behaviours witnessed by HCPs and they demonstrate a potential lack of understanding of behaviour change theory and that the desire to change, and that an individual's ability to change is cyclical (Prochaska and DiClemente, 1982). This is another example where professional training on this topic and aspects of behaviour change may change the views and attitudes of HCPs, which highlights HCPs' duty to undertake adequate training as part of the development of a diet-related intervention for those with psychosis.

A drive for honest and transparent health service delivery is backed by the Care Quality Commission's (CQC) Duty of Candour Regulation 2014, which states that patients have the right to be informed about all aspects of their care (CQC, 2022). The regulation is applicable to all HCPs and applies to patients and members of their care network (CQC, 2022). One of the key components of these regulations is the need for HCPs and services to be open when mistakes are made. Previous data examples cited within this study highlight that HCPs believe that a duty of candour also extends to the provision of food and *"what the wards are feeding them"* (Group B), particularly for those lacking mental capacity to make decisions. If there is potential that the food provided on inpatient wards could lead to weight gain, a physiological change, then it could be argued that a discussion on this should be no less important than a discussion on the effects of medication administered as part of care. These participants feel, based on their respective professional knowledge, that the food provided or consumed by patients within services in their experience, is not always supportive of their health. This is highlighted in some of the earlier examples from the data, such as the conflict they described when patients had gained weight whilst they were unwell with limited capacity and whilst they were under the care of services. The link that participants have made between the duty to be open and honest with respect to dietary habits, suggests that they believe that a diet intervention is fundamentally underpinned by the same standards by which they provide other care for psychosis management. This is important because it suggests that a diet intervention could be embedded clearly into care plans and standard care for those with psychosis, rather than just an add-on strand that supports healthy lifestyles. This is important to note as part of the development and roll out of a diet intervention for psychosis management.

Participants reported a sense of internal conflict when they consider both their duty of care and their duty of candour and they see vulnerable individuals choose an unhealthy option, such as chocolate bars, but note that you cannot take away their right to choose.

> *"it's a lot of your traditional chocolate bars and things like that. The only way you're going to get them to eat the healthy diet is if you don't give them another option, But that's removing choice and you can't really do that. So it is very difficult to try and do." (Group B)*

The role of carers in influencing dietary choices was clearly made too, through their role in supplying unhealthy options to patients on the wards.

> "*It's quite noticeable when they get things brought into them… but it's also some of the energy drinks that they bring on, and it's… And it's probably making them feel better in the short-term, but they don't seem to be able to take on board that it's having any impact in the long-term." (Group B)*

This clearly suggests a role for carers within a diet intervention for psychosis management. If they are not, then they may undo all the benefits that have been delivered to patients through a lack of knowledge or understanding of the implications of the influence they have over dietary behaviours. This example is also interesting in relation to The Duty of Candour Regulation 2014 (CQC, 2022) in terms of discussion with patients as a potential example where staff have a duty to advise both patients and their care network on the potential adverse consequences of these food choices. This demonstrates a clear need to include the views of both patients and carers with regard to the development and delivery of a diet intervention for psychosis management.

The examples cited in relation to the balance between choice and restricting unhealthy diet behaviours parallels the literature on smoking cessation and the implementation of smoke-free policies for inpatient mental health wards by NHS Trusts in the U.K. Smoking is the single largest cause of mortality for those with serious mental illness and data from a National Adult Psychiatric Morbidity Survey conducted in 2007 reported that 42% of all tobacco is smoked by people with a mental disorder (McManus et al., 2010). The Health Act (2006) was passed outlining a ban on smoking in enclosed public spaces, which was followed by The Smoke-free (Exemptions and Vehicles) Regulations 2007, which permitted smoking within mental health units until July 2008. One study conducted at the time of the national smoking ban with medical and non-medical staff (n=16) from two mental health Trusts in England following 'smoke-free' implementation reported that apathy and disregard by staff, who reported that they facilitated patient smoking either covertly, or through a bespoke outdoor area (Ratschen et al., 2010). This was linked to a culture of the need for smoking breaks both within patient and staff groups on the basis that staff felt it calmed patients or that they needed it (Ratschen et al., 2010). The recommendation from the study by Ratschen et al. (2010) was that an exploration of the cultural aspects of professionals' views and support in the form of training for staff and support for patients around smoking cessation would be required in order to effect an attitudinal change within HCPs and patients. A qualitative study was conducted exploring the views of patients and staff within ward areas (n=14) from three Trusts over 10 years following the national smoking ban and following the implementation of smoke-free policies across Mental Health Trusts in England (Ainscough et al., 2021). The findings showed that despite implementation of policies, many of the issues around a lack of support from professionals for smoke free ward areas, which was partly linked to a clear lack of robust smoking cessation support for patients at only 56% of those offered support at the point of admission (Ainscough et al., 2021). It is clear from this related example that institutional, regional or national policies relating to diet intervention must first align with the views of professionals, patients and carers in terms of diet in order for any intervention to be considered and successfully implemented.

It is clear within this theme that the NHS as a health care provider has a duty to support dietary intervention for psychosis management, but that this would require buy-in at all levels, not just from interested HCPs, but also medical professionals and commissioners, which must be supported by national agendas and policies. A diet intervention should also be delivered with transparency and candour. In summary, it was clear there was a duty to facilitate this as part of psychosis care provision and thus embed diet intervention into care plans for patients and should link to patients' care network as they are often responsible for food choices.

6.5 Theme 3: HCPs' perceptions of dietary habits of people with psychosis

Following on from theme two which considered HCPs' sense of duty around diet, theme three comprises data that represents the HCP view that patients struggle with psychosis symptoms, which exacerbates difficulties in selecting and actioning healthy dietary behaviours. There is also a preconception amongst participants that patients struggle through being more disadvantaged than the general population, in terms of socio-economic factors. Furthermore, participants contend that patients struggle due to the inability to prioritise their own health when they are unwell because of the negative symptoms of psychosis, which include features such as a more blunted affect, significantly decreased motivation and difficulty in initiating tasks relative to the general population. The data also indicate some negative judgement towards patients and the choices they make and suggest that some HCPs may not believe that patients can recover from psychosis. This though is balanced with a sense of compassion and protection of patients and a willingness to support them in their psychosis journey.

Several of the HCPs' believed that psychosis symptoms and the effects of medication impact on the key processes that support healthy eating, such as cooking, shopping, and food preparation (Group B) either through a lack of concentration or the inability to prioritise preparing and eating meals (Group D). Data examples suggest that HCPs believe that as a consequence of psychosis, patients are making poorer choices than the general population, such as avoiding cooking and ordering a takeaway (Group A) and that these habits are a consequence of the lifestyles that those with psychosis choose to lead.

> *"I think that some patients have such a poor diet because of their lifestyles that they lead" (Group A)*

These data suggest that patients' struggles may be above and beyond those experienced by the general population. It is widely known that healthy dietary behaviours are difficult to adhere to and maintain for the general population (See Chapter 5, Section 5.11.7.2). To what extent these perceptions are true is unknown because it may be that some of the examples given in the data could be true of anyone in the general population and are not restricted to those experiencing negative psychotic symptoms.

There was evidence of judgement of patients' diet behaviours, albeit from a minority of participants, with implied criticism by HCPs in terms of patients' lifestyle choices and an unfair comparison between patients and the general population with respect to ordering takeaways. Being unwilling to cook and then ordering a takeaway isn't limited to those with psychosis, as this is true for everyone at times. Further data again suggested a sense of negative judgement from participants towards patients with regard to the characteristics of those who experience psychosis.

> *"I think, perhaps, the demographic that traditionally people with psychosis… there are always elements of poor diet and poor nutrition. …It's, I know that can affect anybody, but I do think the demographic is probably, you know, the impacts are from a socio-economic status, with the resources that are available to them, as well." (Group A)*

Another example of this type of judgement was that patients preferred "*processed food*" (Group B), which suggested a negative connotation associated with 'ultra-refined' foods, such as ready meals, snacks and drinks made and marketed through the inclusion of additives to preserve shelf-life (Monterio et al., 2019). Within the data, there were other examples that potentially attached a stigma to patients in relation to their health and diet needs. There was a general sense that patients were looking for a quick fix (Group B) and that they preferred other people to take responsibility for their health and their choices (Group A), including meeting their dietary needs (Group B). Some participants believed this stemmed from patients' unwillingness to view their own health needs as a priority (Group D). It has historically been the case that those with mental health issues, such as psychosis, are more likely to be stigmatised and marginalised within society, which is exacerbated through the negative representation of conditions like schizophrenia within the media (Bowen et al., 2019). There is an assumption that prejudice or negative attitudes are not present within mental health professionals, however studies have indicated that those working in mental health services exhibit similar fears and prejudice as the general population (Nordt et al., 2006). Nordt et al. (2006) reported that psychiatrists, psychologists and nurses exhibited negative stereotypes toward those who are mentally unwell with similar frequency to the general population, one example was an unwillingness to get within close proximity to those with schizophrenia. This reported need for social distance may not be linked to stigma however, this may be based on a knowledge and awareness of the effects of psychosis and the associated risks, indicating sound clinical judgement on the part of the HCP.

One study examining the development of stigma within social work professionals, considered that biases may be a result of upbringing or may be an indicator of professional burnout (Acker and Lawrence, 2009). A recent 10-year strategy aimed to reduce the rising rate of obesity in the U.K. was published by The Obesity Health Alliance (2021). It recommended a need to avoid stigmatising individuals based on their choice of unhealthy foods and snacks and accept that the issue is a systems-wide one with government, commerce and individuals sharing a collective responsibility to act (Obesity Health Alliance, 2021). One explanation for this view is that it stems from a desire protect their patients through finding a justification for their behaviour, or it may represent the general lack of knowledge on diet and diet behaviours represented in Theme 1 (see Section 6.3). Irrespective of the root of biases or potential prejudices which may be affecting the care delivered to patients, this is worthy of exploration during the development of nutrition or diet intervention for psychosis management. Suggestions could include to present the potential for the intervention in such a way to patients that reduces the potential for stigma, such as a means to optimise health, rather than to improve what's not working.

In addition to the potential judgement of diet behaviours, the data also represented that a psychosis-associated reduction in motivation impeded patients' ability to engage in any form of diet support from HCPs (Group C).

> *"People just settle into that bad habit, and not really doing much about accessing services or not...they're not even interested in treatment or anything." (Group A)*

A sense of conflict was apparent within participants between compassion for patients due to the added burden they perceive psychosis brings and irritation and frustration that patients don't engage appropriately in support offered by the HCPs (Group D). HCPs relay a sense of frustration that the patient *"missed the opportunity"* (Group B).

> "*And that makes it very difficult then to kind of help people improve their diet, because you try and encourage people to try foods, but it's whether they've got the motivation to do that or if they just prefer the processed food." (Group B)*

Health-related behaviour change is difficult despite the rise of behaviour change models that can help stratify the approach to encouraging desired behaviours. Kelly and Barker (2016) considered that there are several reasons why behaviour change is difficult for patients including that some HCPs view behaviour changes as 'common sense' or an assumption that people act rationally or that knowledge drives behaviour change. These authors note that knowledge acquisition may support some individuals to change behaviour, but that it will not work for the majority of cases (Kelly and Barker, 2016). These data also suggest that HCPs have informally encouraged or directed patients to healthier behaviours as part of their care, although they perceive it was ineffective due to psychosis symptoms. A published qualitative study examining the views of HCPs on the use and effectiveness of 'informal coercion', also known as techniques to improve adherence to an intervention for mental health patients, suggested a dissonance between the belief that such techniques are inappropriate yet that these are being used in daily practice (Valenti et al., 2015). The findings include that more debate and guidance are required to help develop some regulation and framework of acceptability for the use of informal coercion for healthcare interventions (Valenti et al. 2015).

These views on patients' diet behaviour and a lack of clarity as to whether patients can recover or improve their diets is important to learn ahead of the development of a dietary intervention for psychosis. This is because it suggests that those with experience or providing psychosis treatment will be required to help develop and deliver the intervention, but also that they will require knowledge on effective behaviour change methods and a refresher on what recovery for psychosis may represent. The concept of recovery from psychosis does not, for example, relate to a return to a pre-illness state of health, it relates to the individual regaining and retaining control of their life following illness (Anthony, 1993; Jacob, 2015). Some of the examples presented here suggest that HCPs may not fully believe patients in secondary care are capable of recovering. Furthermore, it suggests that a part of the intervention should consider a co-delivered approach with each patient, exploring individual readiness to change (to avoid *"missed opportunities";* Group B) whilst agreeing achievable goals at the outset, that can then relate to their own psychosis journey and symptoms. This finding is corroborated by data which describes a perception that some HCPs can observe and understand the point when someone is ready to make changes.

> *"You get the clients that do eat that and then the other clients, who might be heading towards, like, a healthier balanced diet where you can actually see how, eventually, they're feeling motivated to actually engage in treatment." (Group A)*

This example is interesting because it implies that this HCP was observing or assessing readiness to change within their patients, however it is likely that this is not something that they were actively doing in a structured way, or on a regular basis as part of the care they were providing. A formal approach to the assessment of readiness to change may be worthy of consideration as part of the development of a diet-related intervention. The outcome of this type of assessment would allow tailored support related to the patient's stage of change. Further learning from these data examples suggests that there is a need for HCPs to find a way to manage their own frustrations relating to patients' ability to change their behaviours. This suggests a need for training for HCPs pre-delivery to patients in order to manage their expectations ahead of diet intervention delivery and suggests a role for peer supervision for HCPs as a part of delivering the diet intervention.

Another interesting perception from participants was that they considered that psychosis leads patients to crave certain foods like as a source of pleasure or comfort, particularly whilst they were unwell (Group D). Participants perceived that patients self-selected these foods as a proxy for pleasure to balance out the unpleasant experience of psychosis.

> *"It's about the pleasure centres of the brain and different parts of hormones that food can change, that affects the brain and affects cravings for certain foods… But I think when people are acutely unwell, especially on the ward, if there is kind of comfort food, they tend to choose those options…I also think, like I say, there might be some people maybe who are maybe looking at food as a source of pleasure, so when you've got a lot of stuff going on that's displeasurable, but maybe the chocolate and the sweets and the crisps that offer the pleasure, maybe that's what they put importance on and getting some pleasure back in life rather than thinking, I need to eat a varied diet." (Group B)*

The concept of eating high-sugar or high-fat foods as a source of pleasure or comfort is well known in the general population (Martin, 2001), possibly the result of learnt behaviour (Kemp et al., 2011). It is interesting however, that HCPs view this as being particularly pertinent for those who are acutely psychotic, especially those staying in inpatient units. The HCPs view that the life of someone with psychosis is "*displeasurable*" (Group B) and lacking in joy when they are unwell is something that could have been explored more in the focus group session. When describing the features of patients' diets, the examples given suggested poor dietary habits, which was viewed negatively by HCPs with implied criticism.

There were perceptions that demonstrated compassion for patients who have limited income and thus may struggle to access nutrient-dense foods (Group A) and as a consequence of limited resources and knowledge may require appropriate support and guidance around healthier choices (Group B; Group D). There was also a sense of concern for the wellbeing of patients who can become obsessed over dietary trends, such as those related to bodybuilding.

> *"People can go to extremes and if it becomes the sole focus rather than anything else, maybe sometimes it's detrimental to some people." (Group C)*

These data suggest a balance to the negative aspects previously articulated within this theme, which imply compassion and empathy to mitigating factors for patients, such as a lack of money to eat well. This is balanced too by a participant's perception that not all patients are the same and that some individuals can become motivated and make some changes.

> *"You get the clients that do eat that and then the other clients, who might be heading towards, like, a healthier balanced diet where you can actually see how, eventually, they're feeling motivated to actually engage in treatment." (Group A)*

It is important to consider that whilst some individuals may take dietary change to an extreme becoming an obsession for them, that shouldn't preclude those individuals from receiving support. These data are important in the development of a diet intervention for psychosis management because they highlight the need for the knowledge passed on to include the importance of mental health and wellbeing and why it's important to receive care. The diet intervention must also then instil a sense of balance to ensure that the limits of healthy eating are understood. Perhaps a diet-related support intervention should consider a monitoring component for those that may become obsessed or may misinterpret the information provided to them. Finally, the diet intervention needs to be developed and delivered in a judgement-free zone to ensure that patients engage and to ensure that they are being treated with sufficient dignity and respect.

This theme helps answer the research question at the centre of this PhD through the indication that a diet intervention for psychosis management is best developed and delivered by HCPs that understand and have experience of caring for those with psychosis. The data suggests that achievable goals and a measure of readiness to change need to be set at the outset of the process and progress towards these should be monitored to support positive behaviour change. HCPs acknowledged that due to their frustration when patients can't make changes, training and regular supervision should be made available to support staff as part of the delivery of the diet intervention.

6.6 Theme 4: Factors to consider when developing and implementing a diet intervention for psychosis

HCPs supported the concept of providing dietary support as part of psychosis treatment, but they indicated some clear factors that should be considered to boost engagement and improve the success of providing dietary care. First of all, participants were clear that diet intervention should start at the beginning of the psychosis journey, such as on the inpatient unit, and should continue throughout. Factors to consider included practical aspects such as that a key diet intervention outcome should be knowledge and skills acquisition for patients, but with tailored options around personal circumstances, budget and methods of engagement. Strategies to boost engagement could include flexibility in terms of times and methods of delivery, such as the use the internet and applications to allow a 24-hour approach.

HCPs believed that dietary support should be considered at the earliest opportunity as part of the psychosis treatment plan, which could help mitigate some of the known metabolic side effects associated with antipsychotic medication, as outlined in Chapter 2, Section 2.6 (Group D). In addition to HCPs placing value on when to intervene, they also believed that there was merit in delivering the intervention in the acute mental health wards (Group B; Group C). HCPs suggested inpatient units were a good place to start basic discussions around diet, because that facilitated the provision of diet intervention at the earliest opportunity and could parallel other treatments, like medication (Group C). Additionally, the ward environment provided patients time to develop new habits and participants believed that patients on the ward are often looking for activities to engage in prior to discharge (Group B). This parallels the published literature citing the importance of pharmacological and psychosocial intervention and treatment at the earliest opportunity for psychosis (Birchwood et al., 1998). Early intervention with psychosis treatment was considered important as a means to support relapse prevention. One challenge though was that some patients would lack capacity to engage in the intervention and would be limited in what information they could process or retain.

> *"I'd be really keen to do some sort of sessions with people, maybe in a group, but some of the problems we've got is that when people come in they're not*

> *well and then when they are well they're not here long usually until they go back into the community." (Group E)*

A diet intervention for psychosis should provide clear, but basic information whilst people are on the ward because they may not be well and may not be able to absorb information that is too complex (Group D). Likewise, a diet intervention may require a design that offers repeated sessions for individuals or provide summaries of previous sessions to improve memory retention (Group D). This too links with previous research citing that repetition of information will improve uptake for those with psychosis (Weiss et al., 2003). One point raised by participants was that the ward may also be a beneficial place to start discussions due to professionals and services being able to control the available food options for patients (Group B). One participant envisages that a further challenge to overcome is the potential that newly acquired healthy diet behaviours may be lost when a patient is discharged, as is the opportunity to access professional support from Occupational Therapists with skills acquisition (Group B). Participants suggest that diet intervention should be accessible to all patients post-discharge in the community.

> *"I know we're on a ward here, but when people are discharged back home either to be alone or to family or whatever, they could do with something then as well. I mean, I think it would help empower them if they had something back out in the community." (Group E)*

One participant suggested that a potential benefit to patient engagement following provision of a diet intervention on the ward because that would then be viewed *"as a normal part of their treatment" (Group C).* This is noteworthy because it implies that diet isn't necessarily viewed currently by services or commissioners as having any value as part of psychosis treatment, but HCPs believe that it is of value. These data indicate that diet should start early and should transcend the psychosis journey, but may also indicate a change in attitude is required to view diet as a respected intervention for psychosis management. This is important to consider as part of the development of a diet intervention for psychosis management.

Some of the HCP participants also expressed a belief that nutrition support, including content and structure should be tailored to the individual (Group C). There was a range of opinions expressed and a series of discussion within groups by participants about whether individual or group intervention was the best form. Some participants viewed group activities, such as cooking, are beneficial due to interaction and co-operation.

> *“Things like cooking, that’s quite useful to do in a group, isn’t it? And again, you’re learning from each other, you’re sharing tasks etc…” (Group D)*

Other participants believed that one-on-one support may be preferred due to individual anxieties in group settings (Group D) and to allow a hyper-personalised approach for patients (Group E; Group C). Some of the examples from the data were noteworthy because despite a lot of spontaneous discussion on the concept that a diet intervention for psychosis management should be hyper-personalised, several of the participants couldn’t articulate a strong justification as to why they believed it should be tailored, with generic phrases like *“a tailored programme just for that person”* (Group C). One individual was clear that the hyper-personalised approach could tailor the diet intervention based on the outcome of an individual patient’s dietary and biochemical assessments.

> *Yeah, iron and vitamin D and B and things like that... it’s the ranges, isn’t it… for that individual.” (Group B)*

The concept of tailoring diet interventions to support individual needs has been seen as a critical aspect of their success and should be considered as part of the roll out of new diet interventions within health care (de Roos and Brennan, 2017). Linked to this, HCP participants within this study also expressed the view that content was an important component of any diet support intervention offered to patients. This would be important to individuals to facilitate their knowledge and skills acquisition, whilst considering their individual circumstances and budgets (Group D). Both the design of a diet intervention and the mode of delivery should allow flexibility for individuals whose lives aren’t stable in terms of housing or the type of equipment that people may have for preparing and cooking meals.

> “*And that’s saying that people are in a stable enough kind of place to be able to do that as well. Some people, their housing isn’t fixed, they haven't got any money, yes.” (Group D)*

Core skills like how to prepare foods, such as vegetables would be helpful (Group B) because these skills have been lost over the last few years (Group E). These data suggest not only the provision of tailored care, but moreover that the diet intervention needs to be delivered with a true understanding of patients as individuals, linking to individual budgets, food preferences and food purchasing habits. One example of the content is to consider healthier alternatives to current eating habits, rather than suggesting large changes.

> *"I suppose it might be something like saying to someone cut down on your takeaways, like cut them down to one day a week to begin with and eat some healthier meals. I mean it doesn't have to be fancy cuisine does it, but it could just be better convenience foods maybe." (Group B)*

This datum is a useful example not only for suggested content, but also suggested an approach, which emphasises that suggesting small changes may be achievable and thus lead to successful behaviour change. These changes should be monitored and thus there was a perceived need to assess the diet of individuals at different timepoints and use improvements to help motivate the individuals (Group B). Other participants gave insight into how the intervention should be structured to maximise the benefits to patients, including employing strategies such as selling the benefits of the intervention to patients for their mental health and not just their physical health (Group C) and acknowledging and then linking to an individual's personal goal, such as weight loss.

> *It's about finding a way maybe of reframing it . Yes, it can help you lose weight, but it's about benefitting the mental health bit as well,. It's about how we can tie that in for people. (Group C)*

These data examples are interesting because these HCP participants all consider the importance of effective communication with patients, as a key part of the successful delivery of care. It also shows the value that HCPs perceive in their own role as the providers of healthcare to patients. HCPs are suggesting that the values that are important by which the diet intervention should be delivered include the need for honestly and openness in terms of giving clear and factual explanations about why diet may be important for psychosis. This is to help educate patients to gain knowledge and ask questions on the topic. The development of a successful therapeutic relationship between HCP and patients seems very important as does the need for open communication within that. The need for a good therapeutic relationship and for clear communication are therefore important recommendations for the development and delivery of a diet intervention.

> *"But if I started the conversations and we just started with very small changes… then that would help." (Group C)*

One of the key factors that HCPs believed would be core to diet support provision for patients is accessibility. They had views that a diet support intervention is managed by HCPs working in services, however they were unsure how feasible this was in terms of pressures on services and staff shortages.

> *"So maybe on a ward, the level of information could be more basic, which perhaps could be facilitated by nursing staff or ward staff, although there won't be enough staff to do it, but that's a separate issue." (Group D)*

Accessibility of the diet intervention by patients outwith standard service hours was also something participants viewed as important. Participants suggested it didn't have to be an out-of-hours service, it could be handouts or a page on the internet (Group E). A blend of face-to-face service provision and out-of-hours digitally focussed diet intervention may best meet the needs of patients (Group D). There were specific suggestions about digital usage, with all groups suggesting Apps as a viable and relatively inexpensive method of providing information, and one suggesting there would be value in an NHS-based App as this would inspire trust in patients.

> *"Yeah, like apps or something like that. People are keen on those at the moment and they're not expensive to buy. I suppose it's knowing which one to get isn't it. I think if the NHS did one, then that would be great for people. (Group D)*

An additional benefit of digital platforms, such as applications is that in addition to being accessible, they can also be interactive and allow for data to be stored and processed, such as recording and mapping dietary habits. This can help an individual track, and reflect on, their progress. It can also provide a reminder or prompt for certain activities, which might be helpful in light of any memory retention issues.

> *"People do like apps… it's something about having that there when that person's gone, so you can check back in… And I guess things like the logging apps are quite useful because they do make you a bit more accountable, don't they? They bring it to the forefront of your mind a little bit more, you do think about it. It's a bit more mindful then, isn't it, what you're eating, rather than the*

> *picking up a packet of crisps. If you think I've got to go and log that then on the app, it does make you a little bit less likely to do it… It reminds you." (Group D).*

It was noted that digital applications are popular at the moment, suggesting that service delivery should be adaptive to the needs of patients and to incorporate new ways of delivering care. This parallels with wider literature and discussion on the topic citing that digital applications are in widespread usage in healthcare settings (Ventola, 2014), however a review of their efficacy at improving health outcomes, comprising 172 RCTs concluded that the evidence was weak and warranted further research with improved methodologies (Iribarren et al., 2021). It was an interesting observation that this HCP felt that one of the benefits of apps is that you are accountable, in other words, it makes you review what you have done, or what you are doing and that in itself can alter your behaviour. One of the participants raises the valid point that patients and services would have to be committed to ensure that service delivery was compatible with newer versions. Some of the advantages these HCPs described from using of technology is that it is accessible to patients at any point of the day, which is helpful as a lot are awake during the night, when normal face-to-face support would be much harder to provide, particularly in the community. They also describe another advantage being that apps can give practical support to their users. A diet intervention for psychosis management could consider assistive technology as part of its delivery. Any application should be developed with users' needs in mind to improve its usage and effectiveness, with features such as a means of engaging with patients and providing support that can be tailored both in terms of content and time of delivery.

Theme 4 suggests that the practical elements of the diet intervention were important to participants. A diet intervention for psychosis management should be started early in the journey, irrespective of the patient's location and should be able to continue throughout the patient's journey. Delivery of the intervention therefore needs to consider aspects such as that patients may have transient capacity and thus may have impaired memory retention. The diet intervention content should lead to knowledge and skills acquisition for patients, which may require session summaries and recaps of previous sessions. Another key aspect of the diet intervention is the need for a sound therapeutic relationship between HCP(s) delivering it and the patient, which will boost engagement and retention. Accessibility is also key to the diet intervention with the need for a tailored approach and a flexible approach to delivery, including the potential for technology to facilitate 24-hour support for patients.

6.7 Chapter Summary

This chapter presented and discussed the findings (four themes) from the qualitative study that sought the views of HCPs on the value of diet intervention for psychosis management. Diet intervention for psychosis management was viewed positively by HCPs, although they acknowledged having little knowledge on the topic. The concept of adequate knowledge, which is evidence-based knowledge for individuals delivering a diet intervention for people with psychosis was important to them to provide a high-quality standard of care and to minimise the potential risk of harm associated with providing misinformation. Knowledge acquisition, in the form of pre-registration or post-registration training was suggested a core part of any future diet intervention, however the implementation of training in practice would require organisational support. HCPs acknowledged that diet was an example of their Duty of Care towards patients, not limited to a duty to correct any physiological deficiency discovered as part of care provision. Their duty extended to advocating healthier choices both for patients in the community and for those in inpatient units. HCPs acknowledged that they had a duty of candour to advise and guide patients in relation to the healthfulness of dietary choices, although they expressed a sense of internal conflict particularly for patients on inpatient wards who do not have capacity to make informed decisions on the meals provided to them.

HCPs viewed that those with psychosis are different from the general population, partly because of the impact of symptoms and that patients don’t prioritise their health. These views may represent a sense of HCPs wanting to protect patients, perhaps though at the expense of fully supporting their recovery, or may represent a negative judgement or an outmoded view that patients aren’t really fully capable of recovery. HCPs are interested in the topic of diet and see merit in exploring a diet intervention for those with psychosis. The findings suggest considerations for the development of a diet intervention including that staff training or the recruitment of staff with specialist knowledge would be required. Furthermore, the development and successful implementation of an intervention to be delivered by NHS services would require organisational support. Other recommendations include that work must be done within NHS organisations to ensure that diet and the provision of food is viewed with more importance and that choices pertaining to food and diet should be subject to the same candour as other healthcare interventions, such as medical interventions, particularly for patients may be lacking in, or have transient, capacity. The final recommendation from this study in the development of a diet intervention for psychosis management is that consideration must be given to the inherent beliefs and judgements that HCPs have on patients in relation to the topic of recovery for those with psychosis and on the topic of current dietary practices.

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7. RESULTS AND DISCUSSION OF PATIENT AND CARERS' VIEWS

This chapter presents the findings and discussion of data pertaining to patients and carers views on the topic of a diet intervention for psychosis management. Using a similar format to the previous chapter, this chapter begins with a description of the participants and then a presentation and discussion of the four themes conceptualised from the data. Excerpts from the data are included throughout the presentation and discussion of the four themes within this chapter, which are annotated using pseudonyms.

7.1 Study Sample

Participants were patients (n=8) or carers (n=6) (for definition of these terms see Chapter 3, Section 3.7.1). All participants that expressed an interest to participate were recruited into the study following screening against the study eligibility criteria. There were no participants that withdrew their consent to participate. There was no known overlap between groups for any of the participants. All participants were community based at the time of the interview. The interviews were conducted at venues of the participants' choice (all chose home) between January 2020 and November 2020 and lasted between 8 and 45 minutes, with total data collected equalling 3 hours and 47 minutes. Recruitment and data collection were paused between March to September 2020 due to national and local restrictions imposed during the Covid-19 pandemic.

7.2 Overview of the conceptualised Patient and Carer Themes

A total of four themes are presented and discussed in this chapter. The process used to construct the themes is described in the practical methods chapter of this thesis (Chapter 5, Section 5.18). The first theme '*What constitutes a healthy diet*', details participants' understanding of what a healthy diet means to them, including the irreplaceable role that food has for people and the desire to eat fresh foods with known provenance. The second theme '*Connection between diet and symptoms*' captures the bi-directional link between diet and psychotic symptoms and describes that the physiological and psychosocial connections between diet and psychosis. *'Empowerment gained from finding my own self-management strategies'* is the third theme and is constructed around data relating to motivation, willpower and the importance of being ready to make changes. Within this theme, participants relay a sense of satisfaction and empowerment through examples of diet-related changes that they believe gave them a sense of pride and satisfaction, which in turn helped their mental wellbeing and improved their psychosis. The fourth theme entitled *'how we envision dietary intervention for psychosis'*, describes participants' vision of dietary intervention for psychosis management. This explores practical elements, such as who, why, what, where and when the intervention should be delivered.

7.3 Theme 1: What constitutes a healthy diet

Within this theme, participants voiced a view on what constituted a healthy diet, however the vernacular was general and indicative of a lack of knowledge on what a healthy diet actually means. Links were drawn to the confusion around dietary information, particularly from the media and commercial companies who are not seen as trustworthy sources of advice on health. Healthy eating as an ideal was synonymous with food of known provenance for some, however the extent to which the ideal was achieved for all was unclear. Also within this theme was a clear view that food was important for all participants and whilst diet supplements may be necessary to prevent or treat nutritional deficiency, there was still a clear role for food in people's lives. This role extended beyond mere energy or nutrition provision, it also linked to benefits of the socio-cultural aspects of food.

Participants were generally happy to voice a view on what they believed constituted a healthy diet. It seemed apparent though that the majority seemed to convey only a basic of surface level awareness of the topic, such as the importance of *"getting your vegetables and… vitamins"* (Lisa, PATIENT). The choice of words expressed by participants to describe what constitutes a healthy diet include 'variety' (Lisa, PATIENT), 'balance' and 'moderation' (John, CARER).

> *"Eating like a balanced diet. So, I need to be eating lots of fruit and veg, home-cooked foods, and enjoying other things like cake and stuff in moderation."*
> *(Alice, PATIENT)*

This vernacular is interesting because it is also part of the vernacular used within current public health messages. This indicates that the source of participants' knowledge may be from viewing the mass media campaigns, such as The Department of Health's 'Change for Life' campaign, launched in 2009 (Department of Health, 2010), which are often very brief advertisements that convey little actual, usable knowledge. Alternatively, the vernacular used may not be acquired through direct influence, but perhaps indirectly through these campaigns' impact on the wider community. A recently published systematic review examined the efficacy of mass media campaigns on health behaviours and found little evidence that these campaigns have demonstrable impact on dietary habits (Stead et al., 2019). The lack of robust evidence therefore suggests that whilst participants can relay what constitutes a healthy diet, it doesn’t mean firstly that they have acquired sufficient knowledge or that they put the advice into practice. This may explain examples in the data where participants have cited a sense of confusion over what constitutes a healthy diet (Lisa, PATIENT) and that the information presented in the media is often contradictory.

> *“it’s so contradicting, I think, as well. Actually, I think it’s really complicated. I mean, you’ve got your basics you know, fruit and veg and meat but, yeah, there’s that much media influence now what you should be doing that it’s all different, people are getting confused, aren’t they.” (Julie, CARER)*

These findings are pertinent to answering the research question at the centre of this PhD because they indicate that participants may have a basic awareness of what constitutes a healthy diet and eating healthily may be an ideal that they would like to follow, but that may not translate into actionable behaviours. A diet intervention for psychosis must be developed with practical strategies inbuilt that firstly ascertain the barriers to behaviour change for patients and carers and then strategies that help them change their behaviour. It is also pertinent to note that it remains unclear to what extent participants would connect the concept of ‘health’ with mental health and wellbeing. Particularly, if their knowledge is rooted in generic public health campaigns, aimed at improving physical health issues, such as heart disease and obesity.

> *“We normally talk about other things, sort of, you know, like diabetes and that kind of thing as being linked to your sort of eating habits or exercise and that, but I've never actually come across or thought about it in terms of mental health… I don’t know if I've ever connected it as such to, you know, that's impacting on, you know, to help your mental health.” (Jack, CARER)*

In contrast then to the concept that participants’ knowledge may have resulted, either directly or indirectly from media campaigns, the media was cited by some participants as a source of annoyance in relation to a healthy diet (Julie, CARER). Some participants perceived that the media distorted the limits of what constituted a healthy diet (John, CARER), and that there was currently insufficient regulation of the advertising of potentially unhealthy or highly processed foods and food supplements (Julie, CARER). Annoyance stems from issues including that claims advertised through the media can be confusing and misleading in terms of what is healthy and what isn’t and from the issue that the media and supermarkets use advertising to exploit their preference of unhealthy foods over healthier foods.

> *“And whenever I'm in the supermarket, there's always an offer on if you buy two bags of crisps…one bag of crisps, you can get another four free or something, rather than fruit and vegetables being the healthier option. And the free…buy one, get one free, I never see that for them, it's always the biscuits and crisps isn't it, seem to be on offer.” (Ruby, CARER)*

This ties in with the recently published Food Foundation report entitled ‘The Broken Plate’, which found that 32% of advertising spend is on unhealthy foods, compared to only 1% on fruit and vegetables (Goudie and Hughes, 2022). The data also indicated the view that they already feel that they are drawn to unhealthy foods because they provide instant gratification, so they would like additional support in the form of price reductions or offers to help them make healthy choices.

> *“In today's society...everything is rammed down your throat. And all the addictive...tastier...well, not tastier, but more instant gratification stuff, is rammed down your throat.” (John, CARER)*

These examples represent those participants’ frustration about the use of advertising and marketing by the media and organisations to sell food, which they feel exploits them as consumers. They also represent a sense of frustration felt by these participants firstly that they allow themselves to be exploited and at their own perceived inability to interpret the information provided to them through these means. It is interesting to note that these examples represent an ideal whereby they would like to be choosing vegetables or fruit, which they perceive as healthy, as opposed to crisps, but they don’t feel they can make those choices. This again indicates that the knowledge acquired through the construction of this theme supports the research question at the centre of this PhD, because it reiterates that practical strategies are required in a developed diet intervention for psychosis. It is clear too that there is a desire within patients and cares to understand and evaluate information around food, so that they themselves could ascertain whether a food was healthy. These strategies could break the barriers that exist to healthier behaviours, such as the financial restrictions or lack of skills required by patients and carers to enjoy more healthy foods.

For some participants, a healthy diet constituted eating food with known provenance, as opposed to processed food (Ruby, CARER; Jo, CARER), which was seen as poorer in quality and perceived health value. It was considered to be beneficial to make meals from scratch so that you *“know exactly what’s in them”* (Chris, PATIENT). There was the belief too that high quality food provided more nutritional value than processed food, which is important because food is more than just a source of energy for the body (Ruby, CARER). These participants adhered to the ideal that a healthy diet was synonymous with good quality food irrespective of the cost.

> *"You know, prioritising… sticking with your local butcher or … fish supplier, which I know the household does.… because that's worth spending additional cash on. Yes, you could get this cheaper somewhere else, but they prefer to have quality food… And that's been again, particularly underscored through COVID." (Jo, CARER)*

It is interesting that participants aligned their dietary behaviours to this ideal, which contrasts with the previously published literature which indicates that the dietary choices of those with psychosis are sub-optimal in comparison to the general population (McCreadie et al., 2005; Dipasquale et al., 2013) and in terms of avoiding deficiencies (Williamson et al., 2015). There are many reasons why these data may contrast to the previously published literature including those previous publications reported on statistical mean intakes, which did not take account of the variety of individual differences or the views of the participants they included. They too may have subscribed to a desire to eat a healthy diet, but couldn't access it at the time. This shows the importance of viewing a phenomenon from different angles to understand the reality and it shows the value to a mixed methods approach research studies to help understand the context of a given situation in relation to study outcomes. It may also be the case that the participants that have elected to engage in this PhD study are naturally aligned to healthier behaviours than the wider population. It may also represent a change over time since the literature was published, due to a variety of reasons, such as the recent Covid-19 pandemic highlighted by Jo (CARER). There is recent evidence that following the pandemic, attitudes toward health and health seeking behaviour have changed following completion of a questionnaire by a cohort of individuals from the United Kingdom general population (n=4978), leading to individuals citing they had increased consumption of fruit and vegetables (n=2445, 49.1%) and attempts to lose weight (n=2413, 48.5%) (Anyanwu et al., 2022). These attempts however did not confer sustained significant weight loss over time (Anyanwu et al., 2022). Irrespective of the rationale for choosing food that is perceived to be high quality, a diet intervention for psychosis management should be able to incorporate this for patients who want to achieve this ideal.

There were mixed views from all participants on whether diet supplementation could form part of what constitutes a healthy diet. Some participants indicated that it could be useful for those with limited time to eat regular meals (Chris, PATIENT) and that it could have a role in preventing or correcting nutritional deficiencies (Lisa, PATIENT). Participants were clear that it should not replace food, which is the best source of nutrients (Jo, CARER).

> “*I've read Ben Hardacre's [Goldacre] Bad Science, and it did make me smile 'cause he's quite scathing on some nutritional supplements, and says actually just eat good food, and there may be something in that… I think there is a point if you eat a good diet, and a balanced diet, then there's no need for supplements.” (Ruby, CARER)*

The data also suggested that the nutrients provided via supplements are sub-standard to those acquired from food in terms of their bioavailability. There was also the implication that taking diet supplements represented an unhealthy behaviour, done only to avoid or correct deficiencies. It was unclear from the data whether participants viewed diet supplements as ameliorative for physical health, mental health or both. This remains a gap in the knowledge base that would be worthy of exploration as part of the development of a diet intervention for psychosis management.

A survey conducted in 2013 with a cohort representative of the U.S. population (n=1579) sought diet supplement users’ views and reasons for usage (Blendon et al., 2013). Of those surveyed, 82.3% said that supplementation was important to them, however this did not connect to a specific health-related condition or goal, although 11.9% reported taking supplements to improve their mental health (Blendon et al., 2013). Lentjes (2019) stated that supplementation use has increased in the U.K. in the last few decades but that it has not necessarily reduced the proportion of the population that are malnourished. One potential reason for this is that the use of diet supplements may be by those that are adequately nourished, but are anxious about their health (Lentjes, 2019), particularly following the increased usage noted in some populations following the Covid-19 pandemic (Mohsen et al., 2021). It may be the case though that individuals who need nutrients may not be able to afford to buy supplements.

Irrespective of whether supplements form part of a healthy diet, there was consensus from the data that whilst supplements may support a person physiologically, they cannot replace the wider role food has in terms of our wellbeing through its socio-cultural role as part of how people connect with each other.

> *"I think food is hugely important and probably not replaceable. You know, it [nutrients] will be best at its source." (Jo, CARER)*

Based on the data within this theme and the acceptability to some participants of supplements to avoid or correct deficiencies, there may be value in exploring the concept of dietary supplementation as part of, but not replacing, a healthy diet as part of a diet intervention for psychosis management. This could be used as a short-term aspect of a diet intervention to correct any nutritional deficiencies whilst supporting patients in the pursuit of fostering longer-term healthier dietary behaviours.

This theme contends that a diet intervention is supported by patients and carers and that it should provide them with a toolkit to support them with healthy eating as part of psychosis management. The toolkit should comprise some knowledge on beneficial foods to eat, strategies, skills and recipes on how best to use foods, whilst accommodating individual circumstances, such as budget and cooking facilities. In addition, the diet intervention should instil within patients the skills to evaluate the information that is provided to them from a range of sources, such as the media or friends. These transferrable skills would help them post-intervention, after it has ceased. A tailored approach was seen as key, which is an approach that may require shorter and longer-term goals, with diet supplementation being an example of a short-term strategy to ameliorate nutritional deficiency whilst working towards longer-term behaviour change.

7.4 Theme 2: The connection between diet, the brain and symptoms

Not all participants reported being aware that there is linkage between the diet, the brain and psychosis symptoms. The data though indicates the existence of a bi-directional relationship between diet, the brain and symptoms, where food consumed can impact on the brain and on symptoms and the impact of symptoms can impact on an individual's diet. There was a belief around foods which had a known impact, some positive and some negative, but that factors such as taste, feelings of comfort or even addiction impacted on the consumption of these. Likewise, participants displayed insight when acknowledging a link between symptoms and the inability to prepare a meal, and that they are aware that this is far from ideal.

There was dissonance in the views of participants regarding whether there was a link between diet, the brain and symptoms. Some participants viewed that the brain is an organ in the body and has a physiological need for nourishment in the same way as the rest of the body (Ruby, CARER), whilst others stated that they didn't know (Jack, CARER; John, CARER). Some individuals felt that they didn't think it would help their mental health, but they were willing to know more (George, PATIENT; Tina, PATIENT). One participant reported a belief that water was good for mental health, but then seemed unsure of the value of their knowledge.

> *"I know drinking water is supposed to be really beneficial for mental health, isn't it. Oh, I don't know really. Maybe it helps the brain, I don't know." (Alice, PATIENT)*

The link was also made by participants of the relationship between food consumption and how they felt, with examples from the data whereby consuming unhealthy foods leaves people feeling *"rubbish"* (Margaret, CARER) and consuming healthy foods can leave you feeling better.

> *"I believe that what you eat really affects your body and your mind. Yeah, I do, yeah. If you're lacking in some vitamins or anything like that, or anything, then your body's not really getting everything it needs…I know I definitely…when I eat well, I know…when I eat the right foods, I can definitely feel the benefit of it…* Sometimes *I think you can just feel what your body needs, when you need something." (Lisa, PATIENT)*

One datum (Lisa) seems to represent a *"definite"* and confident view on the topic, however the other datum (Alice) begins by stating emphatically that they know something, which is immediately followed by them saying that they aren't sure. This illustrates the point that people are not confident in their knowledge, which concords with Cornish and Moraes (2015) who stated that people do intend to make healthier choices, but that a flawed knowledge and limited nutrition literacy hinder more healthy diet choices. In addition to a lack of knowledge on the topic, people are also hindered by the inability to distinguish between credible and unreliable sources of dietary information (Cornish and Moraes, 2015). Another interesting point from these data was the lack of discernible benefit from eating healthily at a personal level. This is important in relation to answering the research question, because it has implications for sustaining engagement with a diet intervention for psychosis and it links to the need for clear, visible outcomes of benefit from eating healthily. Support around what changes could be expected and when, from receiving a diet intervention for psychosis management are important.

There was a disconnect between the brain as a direct influencer on mental health and then a disconnect on the potential impact that healthy eating could have in nourishing the brain and thus impacting on symptoms. One interesting feature from the data was the use of "*they're*" (Margaret) when describing those who eat "*rubbish food*", indicating that this participant is distancing I from this behaviour, however later in the same sentence they switched to imply a personal association with the statement "make you feel rubbish". This may be coincidence, or it may represent some deeper feeling of shame, guilt or negative self-criticism for eating what she perceives to be unhealthy food. These data indicate that the views of some of these participants demonstrate a belief system, which may or may not be based on a sound source of knowledge. In addition to the data representing the view that the brain is an organ that requires nourishment, the data also suggested the view that certain foods, particularly fish (Chris, PATIENT), or fish oil supplements, were beneficial for brain health (Ruby, CARER).

> *"I've heard like tuna can be brain food, like fish, yeah? … It helps with…your muscles in your brain, I think." (Cheryl, PATIENT)*

These data suggest a very basic grasp of knowledge on the topic, with particular example being the use of *"your muscles in your brain"* (Tina, PATIENT). The knowledge of fish impacting the brain doesn't indicate whether participants make the link between brain health and psychosis. Likewise, there is also a query as to whether having a knowledge of something would then impact on their dietary behaviour. In fact, one participant stated a dislike for fish and therefore actively sought out supplements to enjoy the potential health benefit (Ruby, CARER). It is clear therefore that a dietary intervention must take into account the need for personal choice and a discussion on options and preferences with patients and carers.

Jorm et al. (2000) conducted a survey with adults (n=3109) who had sought treatment for depression on their views on the helpfulness of treatments, which included pharmacological, physiological, psychological and alternative therapies. Jorm et al. (2000) concluded that people are generally guided by their own belief system in relation to the efficacy of interventions, which may not be based on a sound knowledge of the subject. The data presented in this theme suggests firstly that a dietary intervention for psychosis should aim to provide a basic knowledge firstly of the link between the brain as an organ which has influence over psychosis symptoms and secondly that as these symptoms are manifested from an organ in the body they can be affected by the food consumed. The data also suggests that part of delivering the dietary intervention could be exploring individuals’ relationships with food to help improve the outcome of dietary change.

When considering the link between the brain, the diet and symptoms, it was also clear that some foods were presumed to have a negative impact on the body and *“they don’t do you any good”* (Lisa, PATIENT), but again there wasn’t clear evidence of sound knowledge from participants that these foods can affect the brain or psychosis symptoms. Irrespective of the perceived negative impact of these foods on their health, participants stated that they consumed them either because simply they enjoyed the taste or because of perceived addictive properties (John, CARER). Examples included sources of chocolate (John, CARER), sugary cakes (Lisa, PATIENT) and caffeine.

> *“Energy drinks I think have a real impact on mental state and physical symptoms as well, like, you know, anxiety, like pulse racing and things like that… I don’t drink them myself but a family member has. And he’s got an addictive personality anyway and he swapped it from alcohol to energy drinks because he thought that was healthier. I then looked into side effects of drinking too many energy drinks and they’re just unreal, just really unhealthy.” (Julie, CARER)*

There are theories published in the wider literature that consider the potential for sugar as an addictive agent. Animal models have demonstrated evidence of sugar dependence and neurological changes similar to those seen with opiate drugs (Avena et al 2008). One review indicated insufficient evidence to support these theories in humans and cited that the animals used to test these models were often selectively bred for sugar preference (Westwater et al., 2016). Westwater et al. (2016) consider that the Food Addiction phenomenon seen linked to obesity and certain eating disorders, following the overconsumption of very palatable (highly processed) foods, adversely impacts on the reward centres in the brain in the same way that drug addiction does. They propose that food addictions, including sugar addiction, is akin to caffeine or nicotine addiction and thus more subtle than heroin or other class A drugs (Westwater et al., 2016). They also report that food addiction in humans goes beyond physiological or biochemical factors and that the social impact is also of high importance (Westwater et al., 2016). Sugary foods are a norm within our society and those with psychosis are known to have higher prevalence relative to the general population of nicotine (Zimmermann et al., 2012) and caffeine consumption (Winston et al., 2005) implying that addictions to foods may follow. Food-related addiction theories may therefore be of relevance to a diet intervention for those with psychosis.

Following the data that suggested food could influence the brain, there was also data that indicated a link in the opposite direction. Some participants suggested that the impact of negative symptoms could lead to an unhelpful cycle of feeling low in mood or *"down in the dumps"* which then meant they ate unhealthy foods, which then exacerbated the low mood (George, PATIENT). Likewise, negative psychosis symptoms presenting as a lack of motivation was perceived as inhibiting a patient's ability to prepare meals, leading to a cycle of ordering and eating unhealthy takeaway or processed foods.

> *"yeah, so…well it's his illness…I'm sure he would engage with people a bit better than he does, but at the minute he seems to…can't see why anybody's bothered, or why he should be bothered, or we're not bothered really, so it's all very negative. It's not as easy [to stay motivated to cook] if you're not cooking for other people, and that kind of thing. Not that they don't want to either, they just can't make that effort really." (Ruby, CARER)*

The positive psychosis symptoms, such as hearing voices were also viewed as being so distracting that on some days patients simply forgot to eat, although on other days they can prepare a decent meal (Lisa, PATIENT). Paranoia, another positive symptom of psychosis, was viewed as directly affecting dietary behaviour, due to the diminished capacity to undertake basic thought processes around the need to eat and drink.

> *"People with psychosis might be paranoid about food and what they're eating as well which could have an impact on their diet...I remember [my family member] was really, really delusional and paranoid and it was really hard to get her to drink any water because she thought there was something in it." (Julie, CARER)*

These participants have clearly indicated that the ability or inability to do diet-related tasks, such as meal planning and preparation was directly linked to a person's psychosis at a given point in time. The data examples related to a lack of motivation though may just represent a general sense of a lack of interest or motivation to cook, perhaps after a tiring day or due to a stressful event. This may not then be linked, or wholly linked, to psychosis. Ruby's example suggests that for her family member the symptoms may consistently be affecting their ability to eat well. A diet intervention for psychosis should encourage and harness patients' insight into their own behavioural patterns in relation to diet, thus tailoring the response and support to suit their own personal circumstances. This bears relevance on the development of a dietary intervention because to be delivered successfully, it would require a knowledge and understanding of symptoms, such as paranoia and delusions and how they related to dietary behaviour in order for anyone delivering the intervention to ensure they supported the individual appropriately. It also highlights the important link that must be made between a diet support intervention and other aspects of psychosis management. It shows too the need that all professionals involved in the delivery of dietary intervention to patients must be able to access and edit patient notes, or at least pertinent notes that may be relevant to diet.

These previous examples about the impact of symptoms demonstrate a level of insight into the link between their psychosis experience and their diet, which exists despite a clear knowledge on the links between diet, the brain and psychosis. Other examples from the data indicate that people use food as a source of pleasure or comfort or to alleviate feelings of sadness.

> *"Well, there's all the things that you hear about, like, comfort eating; when people are sad or stressed, they comfort eat, and eat just rubbish. And I do that, or we do that…. I could [stop it], but at the time it's what just you want or need to do." (John, CARER)*

This datum is interesting for two reasons, firstly because the participant is displaying insight into a link between some foods as a source of comfort for them and that this can provide perceived happiness when they feel sad. Secondly, it is interesting because the participant also acknowledges that this is an unhealthy behaviour and one that they would like to change, but that they at that point in time, they are not ready to change that behaviour. John's insight into comfort eating is also interesting as he alludes that this is as an adaptive behaviour to stress, which links to published literature (Gibson, 2012) and has been associated with psychosis (Malaspina et al., 2019). A recent study examining through questionnaire administration the link between emotions and eating patterns showed that young adults (n-72) were more likely to eat snack or processed foods in response to negative emotions, whereas children (n=53) ate these food types in response to feeling happy (Moss et al., 2021). A dietary intervention for psychosis would potentially benefit from understanding patients' stressors or emotional state at the time a package of support was delivered.

Participants also intimated an indirect link between food and symptoms. Examples of this include that the wider context of diet, such as eating foods for pleasure that lead to weight gain, which can then adversely affect symptoms, self-esteem and the ability to engage in healthy behaviours.

> *“if you’re having an unhealthy diet and….you put weight on, that’s going to have a knock-on effect on your self-esteem. Yeah, I think it’d affect your mood, yeah.” (Julie, CARER)*

Likewise, the wider social and cultural aspects of diet, such as preparing and eating meals together as a group can impact on diet behaviours. There is the consideration that being with others influences the behaviour, which can be positively through a sense of shared motivation to cook a healthy meal, or negatively through following others in engaging in unhealthy eating behaviours.

> *“I don’t know really because like today I've been on my own and all I've had what's sugary is a Cornetto, that's all I've had so far. Sometimes when I'm on my own it can be worse, but then again when I'm with people it could be worse if they are having some sugary stuff, I'm like go on, I'll have some of that, so it could be worse either way really.” (Tina, PATIENT)*

Participants imply that the use of foods that are pleasurable and nice to eat, but still healthy and consideration of a positive socio—cultural dietary environment for patients and carers could encourage more sustained positive health behaviours, which could in turn support psychosis management.

> *“It’s a key part of people’s lives, whether it’s just traditions or social events, it’s a connection, and a very common, connection in any culture or religion, that people gather to eat together. So I think, you know, if we could all survive on diet pills and be perfectly healthy, that’s one thing. But I think we’d all be completely miserable, wouldn’t we, and we’d never replace the opportunity to get together with people and enjoy food.” (Jo, CARER)*

Important to note that Jo believes that the dietary habit of eating food together with other people impacts on the brain leading to increased happiness and mental wellbeing. This view links to published literature, which has long espoused that food is one of the key differentiating factors between cultures and not just a means of survival (Sibal, 2018; Dorrance Hall et al., 2021). There is a clear relationship between food and the human experience because it has always been such a central part of daily life (Jamaludin et al., 2018). The perception that the social and cultural aspects of eating are what improves the happiness and mental wellbeing of an individual is interesting. A positive association between social support and a better diet has been found in a cohort of working age adults (n=640) (Ferranti et al., 2013), suggesting that that social support may encourage healthy eating behaviours. The use of group support therefore may be worthy of consideration for a diet intervention for psychosis management to boost engagement and sustained involvement from participants. Kittler et al. (2012) considered that humans are unique in the animal kingdom with respect to the complexity of food consumption processes, including the acquisition, preparation and individuals involved.

The data presented within this theme may be evidence of a power dynamic existing between the researcher and the participants. This phenomenon has been explored in the literature and relates to participants feeling intimidated by a perceived sense of power held by the researcher, leading to participants saying what the researcher wants to hear (Mulvale et al., 2019). This may not be the case throughout and may not mutually exclude a desire to gain more knowledge on the topic or gain support on the topic if they can see credible evidence of a benefit to psychosis.

A diet intervention for psychosis management must include an explanation of the connection between the brain, as an organ and psychosis symptoms. This may help raise patients’ awareness and understanding of the potential role that diet can play in influencing symptoms. The impact of symptoms on dietary behaviours, such as a lack of concentration hampering the preparation of a meal must be considered in the intervention and strategies to support individuals with these issues are an essential component. These data suggest that participants have some insight into these issues, suggesting a beneficial role in exploring and harnessing these insights to lead to tailored strategies to improve dietary behaviours. Linked to the concept of tailored strategies, it may support individuals to explore their own individual stressors that impact on diet behaviours and likewise, there may be benefit in incorporating group support into a diet intervention for psychosis management to boost engagement patients.

7.5 Theme 3: Empowerment through finding my own Self-Management Strategies

This theme is built upon data which alludes to a sense of pride felt by participants that have actively been able to engage in healthy dietary behaviours, that led them to successful dietary change, irrespective of whether that was with or without support. It is interesting that the examples given that led to success for them are often practically focussed and based on quite small changes to their behaviour. The changes include changing their diet to include more whole foods and less processed foods with altered cooking practices to increase the proportion of vegetables consumed (Cheryl, PATIENT). Other examples of empowerment are less generic and often cite a clear benefit to symptoms associated with psychosis, such as agitation and sleep. Once again, the strategies that these people claim were successful were small strategies, that they felt had a big impact. Strategies included reducing coffee intake, or replacing caffeinated coffee with decaffeinated. There was recognition and insight shown in the data that the success of these strategies is related to being ready to change behaviour and that factors, such as budget are also important factors.

> *"I love coffee and I'm a big coffee drinker. I've recently switched to decaf for evenings and stuff and I find that maybe that's helping me sleep better as well. Caffeine is not as high in the evening, therefore I'm happier to go to sleep, I'm not as agitated, I'm not as fidgety." (Jack, CARER)*

A previous qualitative study that was not focussed on diet, which explored the views of those with psychosis in relation to key factors affecting recovery reported a similar theme to this one. Patients associated recovery as occurring through exploring treatment alternatives to the medical model and that they found value in personal transformation and change strategies (Pitt et al., 2007). Pitt et al. (2007) also reported that those with lived experience would prefer access to the recovery stories of others in a similar situation to help boost their own recovery. The examples collected and presented as part of this study suggest that patients feel empowered from finding their own self-management strategies and thus may be quite proud to share their stories and achievements, which may be helpful to consider as part of a dietary intervention. It may support empowerment and recovery in a way that is valued more than simply receiving support from professionals.

Two of the participants shared the empowerment they had experienced as a result of growing some of their own food, like herbs (Jo, CARER) and the pleasure they felt at being able to provide food for friends and family. Ruby said that she has an allotment, which allows her to eat seasonally and spend time with her family.

> *"So, yes, we both are keen gardeners and work on the allotment together, so the food that we crop we eat. I know I have a mini smile that literally I can have something growing, cooked and on my plate within an hour from cropping it*

> *really, and that does feel nice really. And definitely the taste, so when I've given odd vegetable to families, you know, so that, you know, there's a taste difference [compared with the supermarket]. Well actually it tastes of a carrot rather than just being orange." (Ruby, CARER)*

These examples link to data presented in theme 2 (Section 7.4), which represent action linked to the values or ideals attached to the provenance of food. All of these examples also provide a contrasting perspective on previous literature which reported that those with psychosis make poor dietary choices (McCreadie et al., 2005), providing evidence that those with psychosis are actively engaging in healthier dietary behaviours, such as growing fruits and vegetables. It may be the case a current study assessing the dietary habits of those with psychosis may demonstrate that the eating habits of those with psychosis has changed and there may be an increase in those that have decided to grow their own food. The interest in growing food presented here also ties in with a relatively recent increased interest in 'grow your own' food. This is underscored by examples such as the Milan Urban Food Policy Pact, which encourages urban agriculture (Edmondson et al., 2019) and CoFarm Cambridge: a community developed Limited Company with volunteers growing produce for the benefit of the community (CoFarm Foundation, 2021). This may be something worthy of consideration in a diet intervention because it may provide wider benefits to individuals, such as exercise to support weight management and there may be wider social benefits from an allotment space, for example.

Several of the participants positively relayed experiences of empowerment following their own initiation of diet supplementation regimens as a means to help their health and avoid deficiencies (Ruby, CARER). These included a variety of different supplements, such as fish oils, individual vitamins including vitamin B (Dave, PATIENT), and a composite vitamin and mineral supplement (Lucy, PATIENT). Some participants also said they had tried herbal remedies and diet supplements to improve their health due to the adverse impact they had noted from antipsychotic medication (Lucy, PATIENT; Dave, PATIENT) and that there are wider dietary implications, such as digestion and issues with irregular bowel movements.

> *"Yes, Vitamin B I do, yes, but the problem is I take Vitamin B but the extra sweating I get as a side-effect of medication, I have a smell… I have ginger, ginger helps me with the nausea I get from the medication… Definitely I'd say that ginger helps.* B*ecause I'm on Clozaril, my immune system's compromised,*

> *I have to have a blood test every month. I'm taking Vitamin B, I'm taking Actimel and in the past I've taken Yakult." (Dave, PATIENT)*

These examples from the data are positive because these individuals acknowledge the benefit that they received from medication despite its side-effect profile and they have decided proactively to take action to minimise the impact of side-effects on their own health. Their rationale for diet supplementation was perhaps that whilst they may not have control over symptoms of psychosis, or other physical health issues, they could have some control over their own nutritional status. Diet supplementation may also represent a means of assurance around nutrient consumption, through the lack of knowledge or ability to assess current dietary intake. If a diet intervention for psychosis management can elicit a healthy diet through food, then there may be less desire to supplement the diet. It may also be the case that supplementation based on healthcare professional review may be a warranted strategy for psychosis management. If that is the case, it seems reasonable based on the findings of this PhD, that supplementation as part of a diet intervention would not be met with resistance from patients or carers.

Participants relayed that a key step to the sense of empowerment from self-management required individuals to prioritise their own health and be at a stage where they can utilise support in order to engage in healthy diet-related behaviours. As noted previously (see Chapter 2, Section 2.13), a key factor related to any aspect of behaviour is an individual's ability to change, which can be cyclical. There was some contrasting opinions within the data, suggesting differing viewpoints on this topic. There were participants that stated they had successfully managed to make beneficial changes to aspects of their diet, one whose dietary improvements had *"been easy when you get into the mindset",* and had positively impacted on symptoms like anxiety, improved sleep (Jack, CARER). Another participant reported their struggles with readiness to change, highlighting times of success at improving their diet and a recent stressful event, which led to a setback.

> *"Yes, some workers from my mental health team they took me once, twice... I tried, but I couldn't stick to it at that time, but when I did my diet about two years ago, I really focussed on it and I was able to stick to it, but like I says because of COVID and my friend's problems it's gone downhill now." (Tina, PATIENT)*

Ruby, on the other hand articulated insight with the view that knowing what you should do, doesn't always lead to actionable change in her case.

> *"Well yes, knowing the answer and doing it is a different thing… Well I think it's easy to know what's good and what's not really, but the actual doing it is the difference. So knowing it and doing it are two different things. I don't always practice what I preach, but I do try to eat five a day. So I have little drives with myself where I do make a conscious effort to eat the five a day, and more if I can really. And then I go off grid really, and then don't, and then there's the fruit going off in the bowl that I have to clean up, or throw away really. So, yes, I don't always practice what I preach, but I do try to eat five a day." (Ruby, CARER)*

Within this datum, Ruby also acknowledges that she struggles to change her eating behaviours even though she has the required knowledge to do so. This suggests that behaviour change is cyclical in nature and not linear, suggesting that even though a change can be made, regression back to old habits can occur.

Diclemente and Prochaska (1998) described a 5-stage model of behaviour change, which were precontemplation, contemplation, preparation, action and maintenance. A recent systematic review reported published studies (n=9), which had evaluated the effectiveness of dietary interventions that were based upon theoretical models of change, on whole dietary change in individuals (Timlin et al., 2020). The results of this review were mixed, but the authors believed that the mixed findings were due to the inclusion of studies whose design did not fully apply the theoretical change model (Timlin et al., 2020). The need therefore to incorporate the theory of behaviour change will be important in the development of a diet-related intervention for those with psychosis. This could be through embedding an assessment of readiness to change within the intervention framework to understand in individual's stage of change and tailor support accordingly.

One participant (Tina, PATIENT) displayed insight through an understanding that they weren't able to use the support when it was initially offered but that the information was still helpful when she was ready to change two years later. It is interesting to note the negative impact of the Covid-19 pandemic was cited by them as a factor that prevented their ability to sustain changes. This links to findings from a systematic review of literature, which indicated that social isolation had a negative impact on healthy food preparation (Leigh-Hunt et al., 2017). Published literature also cites that behaviour change is related to an individual's own stage of readiness (See Chapter 2, Section 5.11.7.2). Ruby's earlier example of taking action to eat more fruit and then relapsing back to the precontemplation phase clearly shows her insight that this process is cyclical and not linear. Tina's datum again provides insight into the lack of linear association between time and advancement through the stages, however it also shows that she believes the support she had from mental health services was the catalyst to her actioning a change in behaviour. This may suggest that a diet intervention for psychosis management is best placed within mental health services.

Participants unsurprisingly believed that the ability to engage with positive dietary behaviours was dictated to a certain extent by a participant's access to resources, such as time or money.

> *"I think the problem is where I've supported my brother and cousin… that they haven't got much money, and it's just so much cheaper to go and buy…do a freezer food shop, packets of cheap processed food really that can fill your belly. You know, and if you haven't got any money and you are hungry, you need to fill your belly." (Ruby, CARER)*

Likewise, participants acknowledged that whilst these strategies were empowering, they weren't without effort and sources of frustrations. Examples included that a lot of meals that they perceived as 'healthy' took a lot of time and effort to prepare (Julie, CARER) or required an initial purchase of many ingredients all at one time, which meant that it was costly and thus unrealistic to them (John, CARER). One participant noted their frustration that the patient in their family wouldn't make something simple, they would rather get a delivery of processed, unhealthy food (Ruby, CARER). Some practical suggestions of simple, but healthy meals that can be made with relatively low income may be a beneficial part of a diet intervention used for psychosis management.

There are strategies to eat healthily on a budget, such as using frozen or tinned fruit and vegetables within cooked meals, but they require skills and knowledge. They also require motivation, which is often lacking for those with psychosis. Geographical areas with a mean income lower than the national average, have greater access to unhealthy eating options (Hilmers et al., 2012) and a study has shown that the cost per calorie of healthy foods is almost double the cost of unhealthy foods (mean healthy-to-unhealthy ratio = 1.97 [SD 0.14]) (Kern et al., 2017). There is evidence indicating that the dietary habits of those with psychosis may be poorer than the age-matched general population (Dipasquale et al., 2013) and may be a reason why people make a pragmatic decision to buy cooked food rather than use the electricity. This may be an even greater concern in 2022 and beyond with the removal of the existing fixed price cap for energy prices. In light of these issues, support around improved access to healthy eating, such as upskilling, tips for cooking on a budget and improving the knowledge base should be incorporated into a dietary support intervention.

A contrasting hypothesis related to why family members feel that those with psychosis have greater challenges to overcome with their diet is the side effects of antipsychotic medication, including metabolic consequences leading to diabetes and obesity. Ruby believes that these metabolic issues associated with medication and the stigma attached to body image represent a vicious cycle through reducing the patient's motivation to make changes. An understanding of the motivating factors to engage in a diet behaviour are important and should be a feature of a diet intervention for psychosis management. These factors may not be a reduction in psychosis symptoms, they may be the ability to reduce the psychotropic medication or the perceived benefit to self-image of weight loss.

> *"I think for him some of the medication he's been on has been putting him weight on, that's then made him feel sluggish. It's hard enough for him to talk to anybody, but then to be heavy and the stigma of being overweight, people think you're lazy don't they, whether you are or you're not, whether you're on medications or you're not." (Ruby, CARER)*

One participant believes that it must be hard for someone with psychosis to prepare a healthy meal, when unhealthy foods are more convenient and more readily available. That example suggests the perception that a gulf exists between those with psychosis and those without in terms of the ability to motivate themselves to make healthy diet choices. This is in contrast to an earlier example where the same participant noted that their ability to eat sufficient fruit and vegetables on a daily basis was transient. Part of the development of a diet intervention for psychosis management should consider exploring the reasons why patients and carers believe that those with psychosis have a greater struggle than the wider population. Is there, for example, a greater struggle with diet or is it that members of the care network are over-protective of those with psychosis and could potentially disempower them by not supportively challenging some of these behaviours. Family members can themselves feel disempowered in caring for those with psychosis and family involvement is found to be beneficial to psychosis recovery (Pharoah et al., 2010). It may be that food is one area, particularly in intergenerational carer-patient relationships, where the care giver feels they can have a knowledge of what's best for the patient or that they know the extent of their limitations, e.g. when they are unable to prepare meals.

A diet intervention for psychosis management would benefit from including and sharing positive examples from lived experience whereby patients have managed to make their own changes. Some strategies would be useful to have oversight from HCPs, such as supplementation, to support a safe and appropriate approach. This theme also highlights individual differences and suggests that a tailored approach based on goal setting and behaviour change theory is warranted. Equally, an understanding of motivators that sit behind these changes would also be helpful to explore with patients as part of their psychosis management.

7.6 Theme 4: How we envision dietary intervention for psychosis

This theme indicates that a diet intervention for psychosis management is viewed positively by participants, but there is hesitation due to a lack of knowledge on the benefits it could bring. It was clear that the NHS and mental health services specifically were the recommended, trusted organisation responsible for the delivery of the intervention. Aligned to a trust in mental health services, it was clear that trust was at the centre of a successful diet intervention because a therapeutic relationship was essential, as was continuity in provision from qualified and trained HCPs. Participants didn't want the vulnerability from having to change HCPs throughout the intervention process and were clear that this was a reason for disengagement in other care interventions. The theme also indicates that a flexible and tailored approach is ideal for delivering a diet intervention with psychosis and that digital and assistive technology can support that. There was consensus that the diet intervention should start at the beginning of the psychosis journey, although issues were acknowledged around capacity and the potential therefore for poor memory retention.

Participants believed that those with psychosis should be able to access support around their diet (Alice, PATIENT), particularly as a mechanism to correct nutritional deficiencies and to ameliorate the negative side effects of medication, including weight gain (Lucy, PATIENT), and a consequent reduction in self-esteem and mood.

> *"From the tablets you put weight on; that's going to have a knock-on effect on your self-esteem. Yeah, I think it'd affect your mood, yeah." (Julie, CARER).*

The data represents a positive view around the potential for dietary intervention as part of psychosis management, but it is clear that there is some hesitation and doubt about the extent of the potential benefit. This may be due to a lack of knowledge on why it is beneficial.

> *"I don't think it'll completely get you off your medication, you know, 'cause some people actually do need the medication, but I think it would help a bit." (Margaret, CARER)*

There was clear enthusiasm from all participants irrespective of their level of knowledge on how they envisioned dietary intervention for psychosis, with one participant stating they had tried and failed to access this type of support previously.

> *I think it would be helpful. I think I've looked on NHS for like diets stuff before, and I've never seen anything that massively useful. (John; CARER).*

Participants believed that a dietary intervention for psychosis management should be delivered by a trusted organisation, such as the NHS as opposed to a commercial weight loss company (Julie, CARER), specifically mental health services.

> "*I suppose it could be something that you looked at within a mental health service, you know, because you're already working with the patients anyway and a lot of the side effects can increase, weight gain and things, can't they…. Yeah, I think so, because you could link it to the mental health treatment that they're getting as well." (Julie, CARER)*

The need for a trusted source, such as a healthcare provider suggests that dietary information is confusing and patients and carers feel vulnerable because of their inability to evaluate the information provided to them effectively. The value that patients and carers place in a trusted source is important to note for a future intervention, but it is also an interesting finding because it implies that patients and carers trust NHS services and specifically mental health services as treatment providers.

In addition to the vision that a trustworthy service provider is required to deliver a diet intervention for psychosis management, there was also a clear view that trust was a key feature of whoever delivered the diet intervention (Cheryl, PATIENT; Lisa, PATIENT). The values here suggested that trust and inclusivity were the foundation for a sound therapeutic relationship between professionals and patients or carers. One of the key values described as a core part of the therapeutic relationship was the need to connect with a professional in order to successfully engage with them (Cheryl, PATIENT), which participants suggested can take time (Lisa, PATIENT). This also suggests that continuity of who delivers the intervention is an important consideration as part of the delivery of dietary intervention for psychosis management. These values, which are based on participants' experience, are all considered to be important, including the need for several visits to really *"open up"* and trust someone (Lisa, PATIENT), therefore these should be central to the diet intervention irrespective of the contexts in which it is deployed.

> *"When I'd meet people for the first time, sometimes until I get to know them, I'm not as open with my information. I do try to be, but I think I feel better with somebody I know… But also keeping the same person. Because they get to know you and they get to know…and you get to know them. Then I think you can talk more easily. Obviously making sure you get the right person. I know some people that do have…that have confided in me that they've had, like I say, a psychiatrist or an old…well, to see a psychiatrist perhaps and they've felt like the psychiatrist has made them feel worse afterwards than better." (Lisa, PATIENT).*

These perceived core values to the relationship between patients or carers and healthcare providers link in with published evidence, which report the importance of trust and examples of pro-behaviour such as appropriate self-disclosure in the therapeutic relationship for practitioners in mental health services (Crits-Cristophe et al., 2019). It is logical that patients would be reluctant to disclose how they are feeling, particularly on sensitive topics without a feeling of trust. It is understandable then also that patients would want continuity in terms of the professional giving them support. As the concept of a diet-related intervention for psychosis management remains undeveloped, there is the opportunity to incorporate the learning from this data. A diet intervention for psychosis management must be delivered by trusted professionals and where possible, either the same professional should deliver the intervention to patients, or consideration should be given to a handover period that has been cited as engendering the development of a bond that is critical to a positive therapeutic relationship (Bordin, 1979).

The data also highlights a sense of frustration for patients and carers and the potential for disengagement when services do get it wrong, including when they misjudge whether someone is ready to make changes (Ruby, CARER) because it amplifies a *"feeling of failure"* at not being able to change. The need for services to understand the repercussions to the therapeutic relationship if they get it wrong should be an important consideration in the delivery of dietary intervention for psychosis.

> *"Like when people do…are under somebody, I know when I was first ill with psychosis and it was going back to 2001 when there weren't really OTs and things that… in it then. I just used to see the psychiatrist and because he was that busy, he just used to send a locum. So, every time…or a student or something, and every time…all they were interested in, was just your condition for learning for their own experience and not really giving you any solutions as to how you might get better." (Lisa, PATIENT)*

Data within this theme also indicates the importance of services continuing to attempt engagement with patients who are not ready to make changes in the first instance. There is the inference that a sustained approach as part of the care package is important as part of the service provision.

A part of the perceived vision of delivering a diet intervention for psychosis was that it should use a flexible model for delivery to suit patient and carer needs. Examples of this include the ability to deliver the intervention in people's homes (Alice, PATIENT; Lucy, PATIENT). Furthermore, additional benefit could be gained from assessing the home environment, such as clarification of existing dietary habits in situ, through a check of the types and brands of foods purchased.

> *"I'm sure that when he's been to see them, he'll have been to see them at their clinic. They've not been to his house, and if you went to his house… you see whatever they've got in cupboards, or what's is in somebody's bin." (Ruby, CARER)*

The data examples contend that a poorer standard of health care was provided when professionals fail understand a patient's home environment. This study has helped answer the research question through the new knowledge that patients and carers value a flexible approach and that home visits are not an intrusion, patients and carers are willing to support these. It is interesting to note that home visiting also implies that engagement with care interventions are boosted through face-to-face interaction. This seems important to consider in the development of a diet-related intervention and links to the concept of building trust and a therapeutic relationship with professionals. Tailored care in relation to diet is also important learning from the data, because individuals are all different and therefore some flexibility in delivery locations and methods may benefit engagement with the intervention and lead to an improved outcome.

> *"Yeah, I do. Because I think…sometimes I think it [face-to-face interaction] can have more connection. I am okay doing…obviously with adjusting with COVID now to doing things remotely and by phone and not face to face." (Lisa, PATIENT)*

Linked to the vision of diet intervention for psychosis being accessible in terms of delivery location, data also indicated flexibility around timings as being of importance (Margaret, CARER), such as access outwith normal office hours (Lucy, PATIENT; Jo, CARER).

> *"I guess that can be accessed at any time then, couldn't it?... You could look at it at night or whenever.?... Yeah." (Lucy, PATIENT)*

Participants also expressed the view that linked to flexible timings, there may be a role for technology, such as online (Margaret, CARER) via a dedicated website (Chris, PATIENT), perhaps with someone available at certain times to interact with remotely.

> *"I think digital is definitely, is really handy, something that you know you can easily access is always good but even if you want, an initial assessment discussion… even a person on a phone or something like that would be of benefit." (Jack, CARER)*

Some of the participants also specifically cited that smartphone applications, 'Apps' were also a potentially viable method for accessing a diet intervention for psychosis management. Views included that these could allow interaction with a dietitian with users logging their food intake (Lucy, PATIENT), or swapping recipes and tips (Margaret, CARER) and with another participant citing apps as a means of personalising the intervention to the individual.

> *"If this was any way of making an app a bit more bespoke to yourself, that would be helpful. So if you could make it very bespoke, that would be great, but you definitely just generally need bespoke and that would be, you know…so this…if you're trying to cater for people with X, Y or Z, this is how you can…you know, these are things you can think about, would be useful." (Jo, CARER)*

There were also contrasting views suggesting that there remains a role for human interaction as part of a diet intervention for psychosis management. Data suggested a role for professionals in supporting and maintaining engagement and the therapeutic relationship, alongside providing assurance to patients that the intervention is safe and trustworthy. Likewise, due to the need for accessibility, technology was not envisioned as part of the delivery of dietary intervention by all participants, however. This seems to be linked to a preference for face-to-face to help with interaction (George, PATIENT), but also due to practical constraints, such as a lack of access to a computer or the internet. Some individuals indicated that they haven't got access to computers (Dave, PATIENT) or the internet (Cheryl, PATIENT). One participant said that it didn't have to be a physical meeting, but they would like someone that they could chat with and ask questions (Alice, PATIENT). This might be pertinent at the start of the intervention to help with fact-checking and assurance that they have understood key message and knowledge (George, PATIENT).

Within the theme and linked to the value of flexibility on delivery location of a diet intervention, the data also suggested that the intervention should be tailored to meet the needs and situations of the individual. Participants viewed that diet intervention shouldn't be a blanket approach and that a tailored approach is best (Chris, PATIENT; Dave, PATIENT) and should start with an objective understanding of the individual's current diet through questionnaires, for example (Jack, CARER), rather than making assumptions (Lisa, PATIENT).

One participant advocated patients may benefit on an individual level from peer support through group interaction (Julie, CARER).

> *"And I think it gives you a bit more motivation, especially somebody with mental issues, they're probably going to lack that, yeah, you need that boost and you need peer support as well, I suppose." (Julie, CARER)*

The intervention then could support with ideas for meal plans and practical tips to improve the diet.

> *"I don't know, again I think if it was something that catered a bit more for what the individual sort of, you know, needs, probably would be a way, you know, like maybe a health plan or a, like a, you know, something along those lines, a questionnaire, kind of thing, and kind of kickstart it that way. The only thing I can kind of sort think of is like anything that I've done previously, like, you know, what do you typically eat, what do you typically do and then sort of suggest*

> *meal plans or ideas, maybe sort of along those lines for what do you struggle with." (Jack, CARER)*

These views are interesting because they summarise that people irrespective of similar diagnoses are different and individual and therefore should be treated as such, however that doesn't exclude group interaction. The data was also noteworthy in that whilst participants were willing to relate their view of tailored care with some direct examples, these examples related to physical health conditions, rather than psychosis symptoms. Patients and carers strongly suggested there that they want to know what their diet is like, they also want to be able to track and see what changes they have made. The importance placed by participants on diet intervention commencing with a baseline assessment of their diet and proceeding with an evaluation of change over time feels like a very important finding from this study. Understanding that patients and carers want a tailored approach to meet their needs is an important element within the design and delivery of a diet intervention for psychosis management.

Views were expressed that diet intervention for psychosis management should be initiated early in the psychosis journey (Lisa, PATIENT; Ruby, CARER). Diet intervention delivery could perhaps start on the inpatient wards because people can still retain what is said to them even if they aren't fully able to make changes.

> *"Well really that's right from the start… maybe even in hospital really. I mean I know when they're coming out… I know myself when I was on, and I was only on for a month, that it's a long day. You've not got a lot to do. Then absolutely, if somebody comes on that they can see, because they don't see that many people, they're absolutely dying to be able to talk to someone and they'll take any information that they get. So, maybe even just discussing it on the wards and perhaps getting it into their head. I mean I know that I've…I know like with getting back to work and things, people have discussed things with me when I wasn't quite ready, but I still took it on board and kept all the information. Then when you are ready and you're perhaps getting a bit better you can like take it more into consideration. I suppose it depends as well on the person really and how well they are." (Lisa, PATIENT)*

The need to intervene early is partly a practical point that is supported by wider literature on improved treatment outcomes from early intervention following a psychotic episode (Murphy and Brewer, 2011), but at a deeper level this potentially fits with the rights of patients to access interventions that may boost their recovery and to help empower patients from the start of their journey. The perception may also be that this should be recommended at the early stage to help prevent some of the known metabolic co-morbidities associated with psychosis, such as weight gain (see Chapter 2, Section 2.6). There is insightful acknowledgement linked to this vision of how diet intervention for psychosis should be delivered, in that there will be issues around capacity and memory retention through the acute psychosis. These will need to be considered but should not prevent the delivery of a diet intervention for psychosis management and again links to the need for this to be tailored to individual circumstances.

There were beliefs expressed on who should provide a diet intervention, with the majority of participants clearly stating that professionals located within mental health services were best placed (Cheryl, PATIENT; Dave, PATIENT), perhaps via an identified member within a team (Julie, CARER). Insight was made to the challenges that may pose through current pressures and high workloads for existing staff (Julie, CARER). The data also suggested that specialist knowledge would be required to deliver the intervention (Cheryl, PATIENT), but one that understood the additional struggles for motivation and functioning experienced by those with psychosis.

> *“So perhaps if a CPN, with specialist knowledge on nutrition could come and say look here, let's prepare…or a nutritionist that was a specialist in mental health could say. And then he… could prepare the meal, they could have the wrap instead of the chip sandwich… to see that actually he doesn't have to be putting a pie in the oven, 'cause the 20 minutes that could take, you could have done yourself a healthy wrap and have something fresh and pleasant to taste.” (Ruby, CARER)*

Some participants, on the other hand, believed that there may be a role for members of their family or care network to provide support around diet for patients (Jo, CARER; Lisa, PATIENT). This may relate to the fact that family members can reinforce information and knowledge acquisition at times when professionals aren’t there, and it supports them when preparing meals for the family (Jo, CARER). Support from family and the care network can also be linked to boosting an individual’s motivation to eat well.

> *“I share the house with two friends at the moment now. They’re not here at the moment because they are in Brighton at the moment, they have been for a couple of months, so I’ve done what…basically one of them loves cooking, and*

> *she is quite conscious of health, and so when she's there we eat quite healthy food. I can do, it's just on time really. But she absolutely loves cooking and would spend ages cooking…she really goes to a lot of trouble and she likes to just add different things to it and everything. She's sort of keen on spinach and things like that. Yeah, spinach I think it is. She said it's very good for you and other kind of things like that. But she said they've got a lot of goodness in them. (Lisa, PATIENT)*

These data firstly indicate a role for professionals within NHS services, but they also imply a potential role for familial support for patients from the carers themselves. The latter datum also suggested the broader importance of the social aspect of food for families, e.g. sitting down to a meal together. This answers the research question in that the responsibility for delivering a diet intervention for psychosis management should sit with professionals employed by mental health services, but there may be a role for peer or familial support as part of a successful delivery strategy.

Some of the participants had a clear concept of the content of a diet intervention, with some believing it should include advice on what foods to eat (Chris, PATIENT; Jack, CARER) and meal suggestions to avoid repetition.

> *"The right way to diet I suppose. Ideas for meals. Sometimes we struggle with what meals we should have every week. Sometimes it can get a bit repetitive, so we get a bit fed up and then we go, oh, we'll just have a pizza then. I do anyway." (Dave, PATIENT)*

The content of a diet intervention should also be delivered with factors such as budgetary constraints being considered.

> *"Yeah, well I think to help somebody support…there are cheaper, I mean, you can buy a tin of beans that's…and you can buy half a dozen eggs that are healthier that the more frozen pizzas and pies, and whatever. So I think you can make cheaper substitutes that are, I think, not quite as expensive and would be in somebody's pocket really. So I think it's trying to do what you can with what you've got really and…but be understanding that people want to eat, and are hungry really. So I can understand them not wanting to put the oven on and bake a pasta when they can put, you know…but I mean to…I mean, make easier changes, so don't fry the chips, buy oven ready ones and, you know.*

> *There's nothing quicker, or simpler, I don't think, than an egg, fried, boiled or scrambled." (Ruby, CARER)*

Several of the participants suggested that practical support they considered to be important were education and the provision of information to help them learn and understand better food options for them. It was interesting to see that two of these participants directly relayed a need for ideas on meals, which is interesting as there exists many recipe books and recipe collections online, but what these participants are articulating is that they seek to acquire the ability to evaluate the healthfulness of foods and meals, implying that they haven't currently got this skill. This could be an important point to consider when developing a diet-related intervention for those with psychosis.

These data suggest that patients and carers acknowledge that money is tight, but they are saying they don't just want to eat unhealthy rubbish. This is despite a recently published report by the U.K.'s Food Foundation entitled 'The Broken Plate' cites that the poorest quintile of U.K. households would need to spend 47% of their disposable income on food to meet the Government's healthy diet criteria (Goudie and Hughes, 2022). Likewise, the report cites that healthier foods are three times more expensive than unhealthier foods per unit of energy (Goudie and Hughes, 2022). This report's findings include recommendations to the U.K. government to increase the income of the poorest households and rebalance the cost of food through reducing the price of healthier options (Goudie and Hughes, 2022). In light of these findings, the ideal represented within this theme's data of eating only high-quality, healthy foods may be difficult to achieve, or difficult for all experiencing psychosis to achieve. Whilst influence of these factors may be outwith the scope of a diet intervention for psychosis, the intervention should consider including strategies to ameliorate these issues. These strategies could include advice on batch cooking and freezing meals, or buying and cooking food that has been reduced in price due to being near its expiry date.

Participants considered that practical activities-focussed learning may be a useful strategy to encourage engagement as part of the diet intervention whilst also educating and upskilling patients (Ruby, CARER). Particularly where activities can be tailored to the individual (Jo, CARER). These participants' views were that diet-related support should avoid reliance on theory and should be *"hands-on"* practice-driven to support transference of knowledge and to help with skills acquisition (Ruby, CARER). Furthermore, one participant stated the need for a relaxed atmosphere during the delivery of practical sessions with patients to support knowledge acquisition and reduce patients' anxiety. This participant believed it would help sustain interest and this possibly aid participants' memory retention.

> *"I think he always talks about different kinds of food when he's been on holiday, so if it were connected with something where he was relaxed and that he enjoyed… he'd have to be a fully-fledged participant, not just something that he goes along and watches someone over a kitchen kind of thing or something… So I think if it were connected in that way, he would probably be interested to know more, and interested to understand and remember more." (Jo, CARER)*

This theme informs the research question through indicating that a diet intervention for psychosis management is supported by patients and would be received well. A clear suggestion was that it must start at the beginning of the psychosis journey, irrespective of a patient's location and there should be a continuity of service. The diet intervention should be delivered flexibly with the potential role for digital technology and internet-based applications. The preference expressed by some participants was for face-to-face support, suggesting that a flexible option or a blended approach may work best. The diet intervention should be predicated upon a patient's baseline assessment of their dietary intake and their nutritional status and goals and strategies should be deployed accordingly. The responsibility for delivering the intervention sits with qualified personnel located within mental health services, although there may be a role for group (peer) and carers to support patients. The ultimate aim of the intervention should be to leave patients feeling empowered with the knowledge, skills and confidence to engage in healthier dietary behaviours.

7.7 Chapter Summary

This chapter presented and discussed the four themes that were constructed from the qualitative data collected from patients and carers on the topic of diet and nutrition. The first theme explores the views on what constitutes a healthy diet going beyond a mere evaluation of a list of foods. There are data examples suggesting that patients and carers view diet as having a socio-cultural role and that food quality is important, which contrasts with previously published literature. Data is also presented within the second theme describing views on the potential physiological and psychosocial links between diet and psychosis, although it is unclear whether the connection has been made by participants that a physiological impact on the brain would have any impact on mental health, suggesting and interesting dissonance between the brain and mental health. Theme three describes and discusses the sense of pride and empowerment patients and carers feel when they find behaviour change strategies that work for them.

Theme four describes and discusses the participants’ vision for a diet intervention for psychosis management. The data within these themes should be used to influence the development of a diet-related intervention for the management of psychosis. The extent to which the themes raised in this chapter compare and contrast with the themes identified from the views of HCPs will be explored in Chapter 8, which presents a synthesis of the findings from across this PhD.

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8. SYNTHESIS OF FINDINGS FROM HCP (STUDY 1) AND PATIENT AND CARERS (STUDY 2) STUDIES

This chapter presents and discusses the integrated findings of the two qualitative studies: study 1, which was an exploration of the views of Healthcare Professionals (HCPs) and study 2, which was an exploration of the views of Patients and Carers on the topic of diet intervention for psychosis management. The sequencing of the key parts of this PhD, according to its explanatory sequential mixed-methods design (shown in Figure 1; see Chapter 3, Section 3.4), started with the systematic review and meta-analyses of published RCTs evaluating the efficacy of diet or diet supplement interventions which reported no suitable diet interventions for psychosis management. This finding then informed the focus group (HCP inquiry; study 1) and the semi-structured individual interview (Patient and Carer inquiry; study 2) topic guides. The systematic review is presented and discussed in Chapter 4 and the results and discussion of each qualitative study are presented in Chapter 6 (HCP study) and Chapter 7 (Patient and Carer study). This chapter commences with a summary of the aims and objectives of this PhD and is followed by the findings from both studies, which were integrated using the principles of triangulation (Farmer et al., 2006) and diagrammatically represented as a logic model to facilitate the interpretation and discussion of the findings relative to answering the research question, which is:
“Is there value in providing a diet intervention for the management of psychosis?’.

8.1 Overview of Aims and Objectives of this PhD

The overall aim for the completion of this PhD, was to explore the value of diet intervention as part of the management of psychosis. A diet intervention for psychosis management is conceptualised as a complex intervention because it is likely to have many interacting components and thus meet the definition set out by the MRC in its guidance on the development of complex interventions (Skivington et al., 2021). This PhD is conducted using a Pragmatist philosophy, requiring a mixed-methods research approach. The process of intervention development began, as recommended by the MRC framework, by exploring any existing diet or diet supplement interventions that had been tested for their efficacy in psychosis management, as evidenced by validated measures of psychosis symptoms. Details of the systematic review and meta-analyses are presented in Chapter 7. The review question and aim were as follows:

8.1.1 Review question

> *“To what extent have diet or diet supplement interventions been trialled for efficacy versus placebo for the effective management of psychosis symptoms in individuals aged 14 - 65?”*

8.1.2 Review aim

To review the extent that diet and diet supplements have been trialled for their efficacy at managing psychosis symptoms following the 2005 recommendation to psychiatrists to consider nutrition as part of the treatment of those with psychosis (Department of Health, 2005a).

8.1.3 Impact of the findings from the Systematic Review on this PhD

The outcome of the systematic review was a lack of robust evidence. This finding informed the two subsequent qualitative inquiries that sought the views of key stakeholders: HPCs and Patients and Carers. This study design represented a mixed-methods approach, which is advocated as an initial step in complex intervention development by the MRC Framework (Skivington et al., 2021). The results of the systematic review and meta-analyses conducted on included studies (n=9) indicated that evaluation of study findings, in conjunction with evaluation of studies' internal and external validity, provided insufficient evidence of interventions suitable to warrant implementation within healthcare systems. Incomplete recording and reporting of trial procedures, such as dietary intake during the study and a lack of inclusion of those with substance use disorders, impacted on the generalisability of the findings. There was also a lack of acceptability measurement of these diet supplement interventions, with high attrition rates present in some studies, potentially indicating low acceptability of the trialled diet supplement.

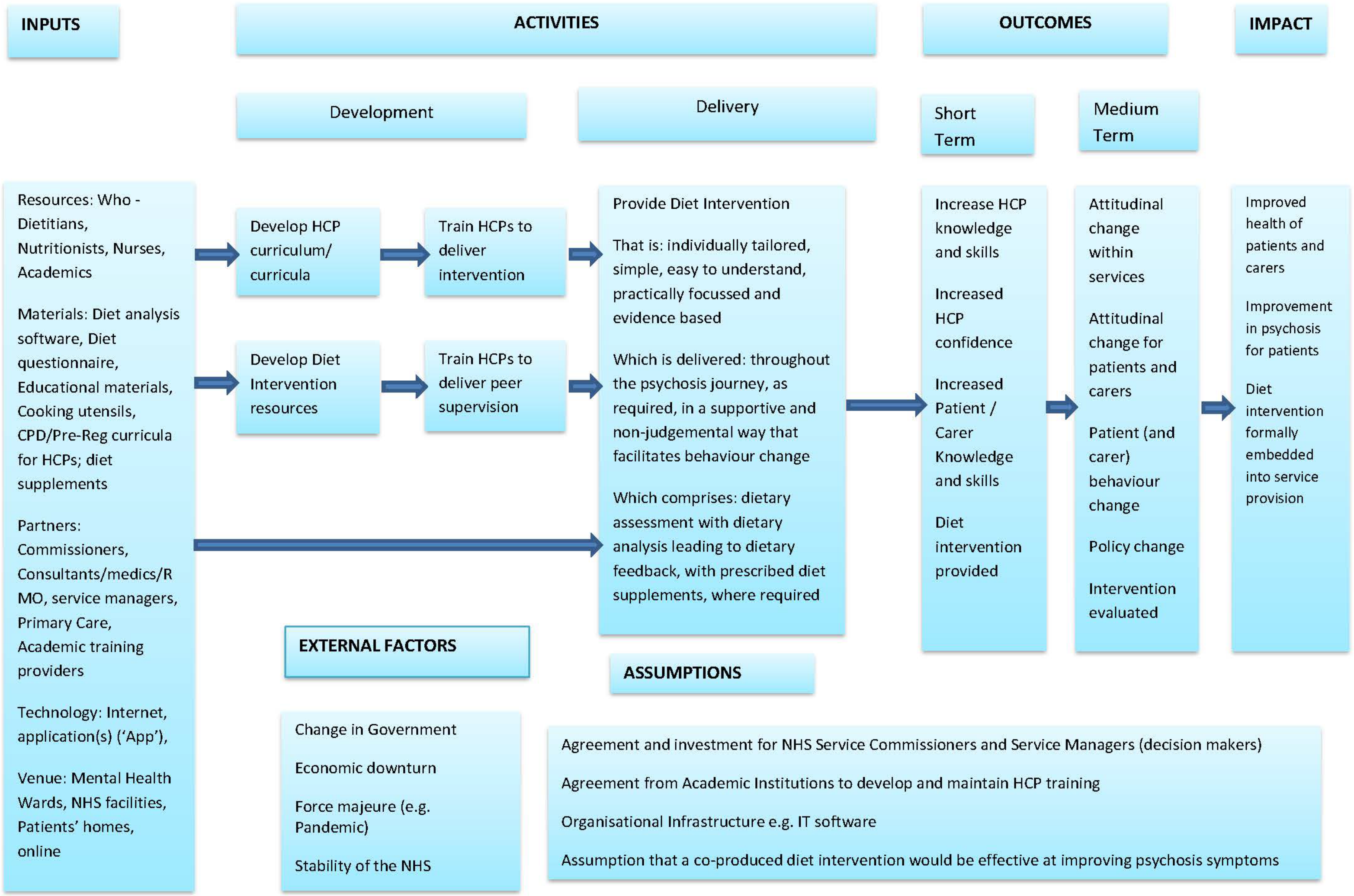
The outcome of the systematic review was no clear dietary intervention that could be implemented for use in current healthcare settings. This informed the subsequent conduct of this PhD which was conducted in conjunction with the MRC guidance on the development of complex interventions (Skivington et al., 2021). The MRC guidance suggests that when the outcome of a literature review is no robust evidence, the suggested next step in the process is to begin development of the complex intervention through consultation with key stakeholders (Skivington et al., 2021). A key part of intervention development is to explore the views of stakeholders to identify the key contextual aspects they deem important relating to, or within a complex healthcare intervention. To achieve this the current knowledge and views of key stakeholders (which were HCPs and Patients and Carers), on the required features of an intervention were explored. The use of qualitative methods, particularly focus groups (HCPs) and semi-structured interviews (Patients and Carers) provided a means to access in-depth accounts of these stakeholders, which were analysed using a thematic analysis approach (Braun and Clarke, 2006) (See Chapter 5, Section 5.18). The resultant data from two qualitative studies were analysed, reported and discussed separately due to the different experiences of HCPs and patients and carers of the same phenomenon (experience of psychosis). These different perspectives when integrated add the necessary contextual elements (programme theory) that would form the key requirements of a diet intervention for psychosis management. The development of programme theory provides a theoretical platform for further development and testing in readiness for the delivery of a diet intervention for psychosis management. Seeking the views of key stakeholders is considered an integral part of the development of a complex healthcare intervention within the MRC Framework (Skivington et al., 2021).

8.1.3.1 Summary of topic guides

The lack of any suitable dietary intervention and the lack of reporting on the acceptability of the trialled diet interventions influenced the focus group and interview topic guides, which were the basis of data collection strategies for these two stakeholder groups (See Appendices 14 and 15). The topics in both guides were centred around exploring what knowledge participants had on any link between diet, food or nutrition and the brain/psychosis symptoms. Likewise, a topic asking participants if they had any knowledge of diet supplements being used for psychosis management and then in what ways did they think, if any, a diet intervention could influence psychosis management.

8.2 Integrated Qualitative findings from Study 1 (HCP) and Study 2 (Patient and Carers)

Integration of findings across the two qualitative studies was conducted using the principles of the Triangulation Protocol (Farmer et al., 2006), described in the theoretical methods chapter (see Chapter 3, Section 3.12) and the practical methods chapter (see Chapter 5, Section 5.19). The integrated findings are presented within this chapter as a Logic Model (Funnell and Rogers, 2011), which comprises the key inputs, activities, outcomes, impact, assumptions and external factors associated with the proposed diet intervention for psychosis management (Funnell and Rogers, 2011; Kaplan and Garrett, 2005; Greenfield et al., 2016). The discussion of the integrated findings within this chapter is designed around the Logic Model’s key elements, which is followed by a discussion of uncertainties following the integrated findings and then the implications of these findings. There are likely to be uncertainties remaining in the totality of knowledge required to develop and deliver a diet intervention for psychosis management. These would require further exploration prior to the development of an intervention ready for piloting, which is outwith the scope of this PhD.



INPUTS

ACTIVITIES

Development

Delivery

OUTCOMES

Short Term

Medium Term

IMPACT

Resources: Who - Dietitians, Nutritionists, Nurses, Academics

Materials: Diet analysis software, Diet questionnaire, Educational materials, Cooking utensils, CPD/Pre-Reg curricula for HCPs; diet supplements

Partners: Commissioners, Consultants/medics/RMO, service managers, Primary Care, Academic training providers

Technology: Internet, application(s) ('App'),

Venue: Mental Health Wards, NHS facilities, Patients' homes, online

Develop HCP curriculum/ curricula

Train HCPs to deliver intervention

Develop Diet Intervention resources

Train HCPs to deliver peer supervision

Provide Diet Intervention

That is: individually tailored, simple, easy to understand, practically focussed and evidence based

Which is delivered: throughout the psychosis journey, as required, in a supportive and non-judgemental way that facilitates behaviour change

Which comprises: dietary assessment with dietary analysis leading to dietary feedback, with prescribed diet supplements, where required

Increase HCP knowledge and skills

Increased HCP confidence

Increased Patient / Carer Knowledge and skills

Diet intervention provided

Attitudinal change within services

Attitudinal change for patients and carers

Patient (and carer) behaviour change

Policy change

Intervention evaluated

Improved health of patients and carers

Improvement in psychosis for patients

Diet intervention formally embedded into service provision

EXTERNAL FACTORS

Change in Government

Economic downturn

Force majeure (e.g. Pandemic)

Stability of the NHS

ASSUMPTIONS

Agreement and investment for NHS Service Commissioners and Service Managers (decision makers)

Agreement from Academic Institutions to develop and maintain HCP training

Organisational Infrastructure e.g. IT software

Assumption that a co-produced diet intervention would be effective at improving psychosis symptoms

Figure 12: Logic Model detailing the core elements of a diet intervention for psychosis management following integrated study findings

8.3 INPUTS

8.3.1 Resources

8.3.1.1. Personnel

There was partial agreement between the two groups that HCPs are well-placed to deliver the diet intervention to patients, although in terms of specific professions, this was an area of dissonance in the findings. This was primarily an example of within-group dissonance from the HCP study. HCP data indicated that some participants would prefer a diet intervention to be delivered by dietitians and nutritionists as specialists in the area, whilst other HCP data indicated that it was part of their role as nurses. Data from the Patient and Carer group was less specific about professional disciplines, but believed that a diet intervention should be delivered by HCPs located within mental health services.

The divergence in the data relating to whose role it would be to support diet intervention for psychosis management may be explained by an anxiety that a lack of topic-specific knowledge leaves HCPs feeling vulnerable to being perceived as lacking ability or incapable or providing good quality care to patients. The debate warrants further exploration from the perspectives of professional identity and role definitions, but it may simply be the case that there is a role for both HCPs qualified in mental health roles and those qualified in nutrition or dietetics roles. One option could be that the development and maintenance of the intervention becomes the responsibility of nutrition/dietetic specialists and the delivery being aligned to mental health trained professionals who are responsible for psychosis management on a daily basis and as such hold a therapeutic relationship with the patients and their families. It is possible that these role discussions could be furthered as part of the onward development of the diet intervention, ahead of the pilot and implementation phases of the diet intervention.

8.3.1.2 Materials

a) Associated with the development and maintenance of an evidence-based diet intervention

This input was sourced from both groups' findings, however the Patient and Carer group's only reference to the development of materials was that staff would require training. The HCP group, however, were more explicit in that they suggested a need for an academically developed and hosted training course that should be included both as a pre-registration option for HCPs and then as CPD option for HCPs thereafter. The data did not provide clear detail on the content or format of the suggested training, probably due partly to participants' general lack of knowledge on the topic. Participants' lack of knowledge on diet intervention isn't surprising when linked back the findings of the systematic review, which were a lack of robust evidence in the peer-reviewed literature on diet intervention for psychosis management. If there isn’t clear evidence out there, it is unsurprising that neither HCPs nor Patients and Carers have robust knowledge on the topic. Further detail on what the content should be and what methods of assessment – theoretical or practical remains an area of silence following the data integration.

b) Associated with objective dietary assessment

There was a range of material inputs suggested by participants across the groups, including dietary questionnaires and materials associated with dietary assessments, such as those recommended as part of the systematic review discussion (see section 4.16.2). Data from both studies indicated a preference for an intervention whereby an objective measure of dietary assessment could be undertaken at baseline to then i) help determine where improvements could be made and then ii) evaluate progress against key targets of goals related to dietary change.

c) Required to provide diet knowledge to patients and carers

There was a clear indication within the data from both groups that educational information should be provided to patients and carers following a dietary assessment. This information ideally should be somewhat tailored to the individual patient with respect to their baseline diet and should lead to an increased knowledge and understanding of healthy foods, with practical suggestions around food swaps and recipe tips. The information provided should also contain practical suggestions that are affordable and could help maximise the individual’s resources, e.g. tips on bulk cooking and storage of foods.

d) Required to provide diet skills to patients and carers

Materials would also be required to facilitate dietary skills acquisition, such as cooking facilities, utensils, cookers and recipes for sessions. These may be required in NHS buildings or facilities, particularly for group sessions, but may also be required within the community for one-to-one sessions with individual patients. An area of silence would be around the potential need for training and policies around the safe usage of this equipment and the maintenance schedule for equipment.

8.3.1.3 Diet supplements

There was also agreement between both datasets that diet supplements did not replace the cultural, societal and biological importance of food. There was, however, concordance between the datasets of the role for prescribed diet supplements, due to their value for correcting nutritional deficiencies, where these had been detected following appropriate assessment by an HCP. It is interesting that both stakeholder groups held a clear belief in the value of diet supplements as important for good health, however the systematic review findings did not indicate robust evidence that diet supplements reduced psychosis symptoms. As both stakeholder groups were keen to include diet supplements within a diet intervention for psychosis management, it would be prudent then to measure and evaluate the effectiveness of any prescribed diet supplements in reducing psychosis symptoms.

8.3.1.4 Partners

Data from the Patient and Carers study suggested that the key partners related to a diet intervention for psychosis management include the NHS and specifically mental health services and academic institutions that can provide appropriate HCP training for delivery of the diet intervention. The HCP study data suggested a more specific list, which included the commissioners of services as decision makers and medics and consultants. There was an indication that medical staff, presumably linked to their potential role as Responsible Medical Officers (RMOs), were important in successfully embedding new elements of care.

8.3.1.5 Technology

Both groups had strong views that there may be a role for technology in the delivery of a diet intervention for psychosis management, with both the internet and specific applications (‘apps’) being cited as a potential vehicle for this. There were several participants from both groups that volunteered a role for technology, however there was dissonance with data from both groups suggesting that they did not use the internet and that it could not replace a face-to-face service with professionals. Several of the participants suggested a blended option that could make use of personnel for face-to-face appointments, but then a technological internet-based source of support, potentially including peer support that could be accessible 24 hours a day. There were areas of silence relating to key operational requirements for such an option, such as the potential need for safeguarding of vulnerable individuals and the need to monitor inappropriate content or wrong information.

8.3.1.6 Venue

There was a clear indication from both datasets that a diet intervention should be delivered as early as possible in the psychosis journey and should be accessible throughout it. In line with that, there was a need for a range of venues to be considered within the delivery of the intervention, including within the mental health wards and then accessible out in the community, within people’s houses. This was cited by data from both groups as a good venue because it helped the HCP understand

and tailor advice and support to the individual’s own facilities. Data relating to the venues for diet intervention to be delivered also relate in part to the technological resources cited above. Some Patient and Carer participants wanted a digital platform for some or all of the diet intervention delivery.

The integrated findings present a comprehensive list of the requirements for the development and then delivery of a diet intervention for psychosis management, which is representative of inputs required for complex intervention delivery (O’Cathain et al., 2019; Sohn et al., 2020). The inputs detailed in this Logic Model (see Figure 12) may not, however, represent an exhaustive list and some may require further elucidation and discussion. One example of this is a source of funding for the development and delivery of the diet intervention. This is pertinent because an underestimation of the funding required can have a large impact on the consequent activities, ouctomes and impact of an intervention (Sohn et al., 2020). Intervention development must be a dynamic and iterative process (O’Cathain et al., 2019) and thus the list of resources is likely to change throughout the development phase of the intervention.

8.4 ACTIVITIES

8.4.1 Development of HCP training and ongoing competency assessment

This activity relates firstly to the development of a diet intervention, with an ongoing cycle to ensure that HCPs remain competent to deliver the intervention. This ties in with Klaic et al. (2022), who suggested that the implementation of a successful healthcare intervention must consider the process for its sustainability as part of the development phase. Both groups were in agreement that staff needed to be appropriately trained to deliver the intervention, which ties in with the literature that training is important for an HCPs’ topic-based knowledge (Vasiloglou et al., 2019) and for the confidence that sound evidence-based training brings to the individual’s practice (Murphy et al., 2015). The preference from the HCP findings was for training to be through an accredited source like a pre- or post-registration university course. The findings indicated that the required knowledge for HCPs who deliver the intervention included information on which foods and nutrients maintain mental health and any key interactions between foods and nutrients, to avoid the risk to patients from misinformation.

HCPs also identified that an important factor for them would be assurance that they have met a certain standard following receipt of the initial training and any regular (e.g. annual) update. This would then be a clear indication that HCPs or whoever had received the training would be sufficiently qualified at the end of the training and would remain so through appropriately regulated CPD. This is to protect the patient and carer recipients, but also the HCPs in terms of their own indemnity. HCP data implied that they may be anxious to deliver a diet intervention citing examples such as the fear of providing misinformation through a lack of specialist knowledge, such as suggesting foods for brain health that may adversely impact on diabetes, and the fear of damaging the therapeutic relationship through mentioning nutrition and diet. These fears may represent a lack of knowledge, which could be addressed through training, or simply anxiety around a change in professional practice. One qualitative study conducted in Sweden, sought to explore the key characteristics of successful healthcare intervention implementation with 30 HCP participants (Nilsen et al., 2020). The authors reported three domains that helped reduce HCP anxiety around the implementation of new health interventions, namely valuing the change, influencing, and being prepared for the change (Nilsen et al., 2020). This is pertinent to the development of the diet intervention for psychosis management because is strongly suggests a role for continued HCP engagement throughout the development and implementation phases.

The HCP study findings may also represent concerns around workload and working in services that are already busy, as NHS mental health services are overstretched. The latter point may explain the data which indicated that HCPs viewed that buy-in from senior medical staff within organisations would be essential to the successful implementation and longevity of diet intervention for psychosis. This echoes the published literature, with one systematic review of qualitative studies (n=15), which explored the views of commissioners, healthcare managers and HCPs on the NHS Health Check programme indicating that understanding the views of commissioners and managers were critical to the successful implementation and delivery of the programme (Mills et al., 2017).

It was clear from the integrated findings that appropriate training was required, however as both groups acknowledged a limited understanding of the links between diet and psychosis, there was limited detail on who would have the knowledge and skills to develop the training course materials. Likewise, what would the process be for updating the intervention to make sure that it stayed relevant and evidence-based. It is not wholly unexpected that this is an area of silence in the findings as there was no direct questioning related to diet intervention development and there was no robust evidence indicating effective diet intervention from the systematic review findings. This is area of silence within the integrated findings and is listed as an assumption within the Logic Model (see Figure 12), which is that academic institutions would be interested and willing to develop and deliver pre-registration or CPD training on diet for psychosis management to HCPs. This would require a presentation of the evidence to them and may require identification of a funding source prior to exploration of this. It may be worthwhile linking in with Health Education England as a source of funding for the training of HCPs in diet for psychosis management. It may be necessary for those who are developing a diet intervention for psychosis management to consider who else could develop and deliver the training if academics, as suggested by the HCP findings, are not interested.

8.4.2 Development of Diet intervention resources

Following the integration of data as presented as a Logic Model (see Figure 12) there was a clear need cited for development of the content and format of any practical sessions for patients, such as cooking and skills acquisition. Neither group suggested who should develop the resources, or who should develop sessional content for skills-based session, but HCPs suggested that taught materials could be developed using co-production and should include examples from lived experience. Patients and carers wanted resources that provided them with more knowledge that linked their diet to psychosis rather than being limited to information related to their physical health. They also felt that any information about diet and mental health should come from trusted sources, such as the NHS. They believed themselves to be vulnerable to marketing from diet-related companies with a vested interest in making money, e.g. Slimming World. This suggests that both groups would see value in the co-production of resources, because they see value in the expertise provided by NHS professionals and provided through the lived experience of Patients and Carers.

Findings from both groups suggest that the content of resources should include helpful examples of dietary change related to what to buy, how to prepare and cook certain foods and meals and how to store it is likely to boost engagement and lead to improved outcomes. These data are helpful to begin the development of a diet intervention, although more detail would be required from the individuals who will develop the diet intervention. Patients and carers had stronger views, furnished with more practical detail, on intervention development than the HCPs, which is interesting because is suggests that they are enthusiasm and engagement in a diet intervention for psychosis management.

An important consideration as part of developing diet intervention resources is that the intervention is structured in such a way that an individual's progress, or behaviour change, can be charted and monitored. Both groups were keen that being able to see change over time was beneficial and acted as a motivator for patients to continue with behaviour change. This also suggests that the structure for access to the intervention should include an assessment of the individual’s stage of readiness to change their behaviour, which is an important predictor of change outcomes (Krebs et al., 2018). Whether this evaluation is managed by the individual patient and/or their carer or is managed in conjunction with HCPs delivering the training remains unclear and is worthy of exploration with stakeholders. Co-production might also help ensure that the materials are accessible to the intended audience, but there are examples from the patient and carer data, such as noting that the vernacular they used to describe healthy diet and healthy dietary behaviours should be aligned to public health vernacular, e.g. ‘balance’ and ‘variety’.

One of the areas of silence across both studies’ findings within the development phase of a diet intervention is any concept of how long it would take to develop a diet intervention. This is cited as one of the key factors to determine as part of the actions for developing a new complex intervention (O’Cathain et al., 2019). It may be that this is a point that warrants further discussion with key stakeholder groups, including those involved in the development and delivery of training for HCPs.

8.4.3 Delivery

8.4.3.1 Need for an evidence-based, easy to follow diet intervention

The integrated data built a comprehensive picture of activities and processes necessary for the delivery of a diet-related intervention for psychosis management. An outcome from the integrated findings was that a pre-requisite of the delivery of the intervention was that is easy to understand and evidence-based. These pre-requisites are important because they suggest that any intervention must be based on verifiable evidence, yet must be relatively easy to understand and follow, otherwise it may fail. The need for a diet intervention for psychosis management to be co-produced designed whilst incorporating pertinent evidence also ties in with other successful interventions that have been developed in line with the MRC Framework for complex interventions, such as the “Let’s Prevent” intervention (Troughton et al., 2016). One specific example from the Let’s Prevent intervention aimed at diabetes prevention that resonate with the findings from this PhD, include that evidence-based content for educational sessions delivered to patients must be presented and delivered in a manner whereby the content is truly accessible to patients (Troughton et al., 2016).

There are examples from the integrated HCP and Patient and Carer findings where individuals highlighting the importance of clarity in relation to information provided. Examples included how confusing participants considered healthy eating to be and that the diet intervention should be interactive and include demonstrations and skills acquisition components. This is because without the interactivity there would be poorer understanding and poor engagement, reducing the diet intervention's potential for success. The data, particularly from the Patient and Carers group suggested that the media played a role in the confusion associated with what was and what wasn't good dietary behaviours. To that end, a diet intervention provided by, and delivered within NHS mental health services should be accessible for patients, irrespective of their capacity and their ability to concentrate, and may want to consider patients' level of health literacy (Schapira et al., 2017).

In parallel to the delivery of a diet intervention that leads to the acquisition of new skills and knowledge, the findings from both groups suggest that an intervention must also address erroneous knowledge and dispel myths currently held by recipients, such as that some foods are wholly bad and should be avoided. The issue of false beliefs relating to diet must be addressed as part of dietary change strategies and is a commonly part of dietetic practice worldwide (Lesser et al., 2015). Synthesised findings also suggest that the diet intervention should strengthen areas where people have some knowledge but are unsure of its origins. When these examples were cited in the data they were followed by a question, such as *"isn't it?"* One interesting example of this is that participants from both groups knew of a link between fish and the brain, which may link back to the post-war era when cod liver oil supplementation was advocated for children, or it simply represent an area of common knowledge in mental health settings. Likewise, it is interesting that despite knowing about potential benefit from fish, this has not necessarily translated into a change in behaviour in practice for these individuals.

There are also examples from the data whereby individuals (patients) may have retained only parts of any knowledge relayed to them. This may be of particular relevance in relation to the overall efficacy of providing a diet intervention to individuals when they are acutely unwell with psychosis, because memory retention issues are well documented for those with psychosis (Avery et al., 2021). Likewise, skills and/or knowledge attrition is an expected part of psychosis, therefore an intervention must be delivered in such a way that it can a) periodically check memory retention and b) have a mechanism whereby skills or knowledge 'refreshers' can be provided as part of the intervention delivery, as required. Ley (1988) tendered a model of communication between HCPs and patients to encourage memory recall because a high proportion of information passed onto patients isn't remembered, or remembered correctly (Ley, 1988). The model indicates that in order to achieve treatment adherence, a cycle of memory recall to determine whether a satisfactory understanding has occurred is required (Ley, 1988). Checking the uptake and retention of information will be an important feature to incorporate in the diet intervention for psychosis management and should be part of the evaluation of the pilot delivery phase of the intervention.

The concept of an evidence-based intervention has existed for decades (Masic et al., 2008), however data from both groups suggested that the intervention provided to each individual should reach beyond the published evidence-based and should be bespoke and personalised to objective evidence collected from the individual’s own diet. This is an emerging area of interest in both the fields of psychiatry (Fusar-Poli et al., 2022) and diet intervention (Wang and Hu, 2018). The integrated findings included specific examples of data sources such as diet questionnaires and biological indices in the form of nutritional biomarkers, e.g. blood levels of vitamins and other nutrients. Some HCPs, however gave examples of diet intervention that they were providing routinely. This is interesting because it could arguably contrast with their view that they didn’t feel they had enough knowledge or confidence to provide diet-related intervention effectively. It may also suggest that an unintended consequence of developing a formal intervention is that some HCPs who aren’t trained, or in a designated diet intervention delivery role may lose confidence in providing any informal diet intervention. To that end an important area to discuss further would be that if diet intervention is defined as a complex healthcare intervention, a decision would be required whether there is any scope for ad hoc or anecdotal discussion on diet, which may interfere with the more formal intervention package, because to what extent can this be divorced from standard care (e.g. have you got enough food in this week). Also, if a formal intervention exists then a clear list of competencies would be required for individuals who would provide that intervention. There would also need to be a mechanism to evaluate an individual’s ability to deliver the intervention and to ensure that there was sufficient maintenance of said competencies through CPD activity. Furthermore, what repercussions should there be for someone who, after a diet intervention is developed, misinforms a patient either through negligence or through malicious intent.

8.4.3.2 Need for practically focussed diet intervention supporting knowledge and skills acquisition and healthy diet behaviours

The integrated data also indicated a preference for practically focussed learning for patients and carers, both for skills and knowledge acquisition. This included findings from both group suggesting a role for group skills-based sessions, e.g. cooking, due to the value in peer support. It was noted though that there should be the option for individuals to participate in 1-2-1 sessions too. Participants suggested the need for hands-on learning as being of value to encourage and maintain engagement. There was convergence on these processes across the data. These data provide understanding of the context within which a dietary intervention ought to be delivered. The suggested need for knowledge and skills acquisition ties in with findings from a diet intervention aimed at improving early years nutrition (Watt et al., 2014), which was developed in line with the MRC Framework for complex interventions (Craig et al., 2008). The findings from stakeholder engagement within the developmental phase, which then informed the pilot RCT, included that information leaflets would not be enough to effect change and that practical support would be required to increase knowledge, skills and thus confidence in parents (Watt et al., 2014).

Synthesised findings from the two qualitative studies in this PhD, suggested that the practical support and knowledge offered should relate to individualised diet behaviours. The findings suggested that following an assessment of an individual's dietary intake, the dietary intervention ought to then build upon the factors or outcomes that require a change by the individual. This should then be followed by an evaluation of progress against these outcomes of the intervention at given timepoints. There are examples from the integrated findings of the importance of considering the circumstances of the individual with psychosis and being able to tailor the intervention to fit. Examples are the need to consider individual budgets, living situations and cooking facilities. Likewise, an individual's psychosis symptoms should be considered, such as a lack of concentration doesn't align well with preparing or cooking complex meals.

It is clear as a researcher with knowledge about nutrition and healthy dietary options that specific options like swapping meat for fish and increasing the proportion of vegetables consumed will improve the nutritional quality of the diet. Likewise, it is clear that there is a clear evidence-based rationale linking diet to brain function and psychosis, as described in the Background chapter (Chapter 2). One of the issues alluded to in the integrated findings from both groups, is that even if an individual is provided with this knowledge, that doesn't always translate into behaviour change, suggesting that the development and delivery of a diet intervention for psychosis management must be linked to behaviour change theory.

8.4.3.3 Delivered throughout the psychosis journey and irrespective of setting

Both participant groups suggested a dietary intervention for psychosis management should be delivered early in the psychosis journey and thus should be flexible in terms of setting, e.g. for patients at home, or on an inpatient ward. There was clear convergence too on the need for diet-related intervention to be delivered to patients irrespective of residential location and a mechanism should be in place to ensure continuous provision of this service throughout the psychosis management pathway, with a seamless transition throughout services. The provision of a cross-service diet intervention accessible at all stages of the psychosis journey would require nuanced or adapted processes to improve knowledge and skills influencing behaviour change, dependent on the contextual factors inherent to that situation. An example of this is a different process assessing dietary habits for a patient on the ward, compared to assessing the habits of that patient in their own home. This approach aligns with the early intervention in psychosis ethos, which has been described as the systematic delivery of increased knowledge on an incremental basis, as opposed to expecting a dramatic or quick breakthrough (McGorry et al., 2008). This potentially indicates that a diet intervention delivered throughout the psychosis journey and irrespective of patient location would fit well with the existing service provision model in the United Kingdom.

Evident in both datasets was a desire for the provision of dietary intervention for psychosis management to extend beyond the patient and to include the care network. This links with the concept that the duty of care doesn't just extend to patients, it also extends to members of the care network, such as family or friends. Members of the care network should be included in the process as it the outcomes of dietary change may benefit from a whole family or approach. This is because patients may be really willing to cook, but if they haven't got control of their own budget or aren't buying the shopping or aren't allowed to cook in their home, then they won't be able to make or sustain any dietary changes and certainly won't be left feeling empowered as part of the intervention.

8.4.3.4 Delivered flexibly, whilst adhering to Professional and Organisational values

The data across both studies, but most notably the HCP study indicate the importance of flexibility within the structure and organisation of intervention delivery. This aligns with Skivington et al. (2021) who suggest that the intervention can and should be flexible in terms of who and where it is delivered, but that it also requires theoretical deconstruction up-front to agree the components where variation is permitted and prohibited. This supports the delivery of an intervention across a range of contexts, whilst maintaining the integrity of the core components of the intervention (Skivington et al., 2021). HCPs believe that a diet-related intervention for psychosis management should fit within their core values, e.g. to provide a holistic approach to care and within the values core to professionalism, such as the provision of quality care safely, whilst reducing judgement and stigma.

a) Provision of quality care

One aspect of the data was an example where HCPs feel that appropriate the diet intervention should comprise objective measurements, which can help benchmark the quality of the care provided. It remains unclear from the data what and where these mechanisms are required so that might be a suggested next step as part of the onward discussions following this PhD.

b) Accessible to all

A flexible approach was required from services and commissioners to facilitate and embed the diet intervention within organisations effectively. An example of this is that individuals shouldn't be excluded for failing to attend or engage with the intervention or its components, as can be the case for some interventions.

c) Free from judgement or stigma

There were examples from the integrated findings from both stakeholder groups of negative attitudes towards dietary choices of those with psychosis and a preference that the diet intervention be delivered free from judgement of individuals' choices or circumstances. This is noteworthy because it indicates that HCPs believe in values-based practice. There was a similar sentiment in the Patient and Carer findings with a source of frustration being cited against services and professionals who seemed judgemental or disinterested. This also led to a disengagement from those professionals, interventions, and services. It is clear from the integrated findings that the delivery of non-judgemental diet intervention will be critical to sustaining engagement and consequent behaviour change. This is echoed in the published literature, with recommendations for HCPs to consider the appropriate usage of moral judgements as part of the delivery of compassionate care (Hill, 2010).

There may be a need for HCPs and patients and carers to explore a mutually agreed definition of when is it appropriate to make a clinical judgement related to diet and when then is it seen as derogatory and not acceptable or when it may induce feelings of guilt or shame. Also, a mutually agreed plan for when and how that should be relayed to patients and carers as part of the diet assessment feedback process. Some participants indicated that they know there is an almost instant bad effect from eating/binging on rubbish food, but they perceived that healthy eating takes longer to show the desired effect, or may not even show a measurable effect. That is a hard sell then in terms of engagement and so links to the need that diet intervention should have strategies that encourage and motivate individuals to make and maintain changes. This could be explored further with stakeholders following on from the PhD.

d) Linked to Behaviour Change theory

Perhaps some of the negative judgement relayed from HCPs may stem from a sense of wanting what is best for patients and thus frustration that individuals could not change their behaviour, as directed by the HCPs. The delivery of the diet intervention may benefit from being rooted in an appropriate behaviour change theory, such as the transtheoretical model (TTM) (Prochaska and DiClemente, 1982). The TTM proposes that behaviour change will happen when an individual engages in the right activities at the right time (Prochaska and DiClemente, 1982). The TTM suggests that there are five key stages of change: precontemplation, contemplation, preparation, action and maintenance and an individual can cycle forward and backward through these stages (DiClemente et al., 1991). This model is one of the most commonly used in dietary interventions, however an objective assessment of which stage an individual is a key component (Spencer et al., 2007). This was evident from the findings of a pilot study evaluating the impact on behaviour change of a psychologically tailored nutritional intervention for adults with psychosis, compared to motivational interviewing and treatment as usual (n=73) (Fulton et al., 2019). Although no results were significant, the psychologically tailored nutritional group demonstrated both progression and regression in their readiness to change their eating habits (Fulton et al., 2019). One of the authors' conclusions suggested that if someone isn't ready to change when commencing a behaviour change intervention, they can regress further back than their baseline stage (Fulton et al., 2019). In line with the key components of behaviour, this suggests that the stage of change is of importance for an individual's care and that there needs to be the opportunity to have access to the diet intervention as a point when this is likely to be successful. This was corroborated by the integrated HCP and Patient and Carer findings, which reiterated that individuals shouldn't be penalised if they cannot make changes at a point in time and should be allowed to reengage when they are ready.

e) Duty to act safely and within professional role boundaries

HCPs gave several examples of the need for them to have access to evidence-based knowledge to support them in delivering diet-related intervention due to their inherent duty to provide care safely to patients and carers. This aligns to their professional standards, codes of conduct and to upholding organisational values. Additionally, they also believed that diet intervention should be enacted with a duty of candour and the duty to advocate in relation to diet for patients who are lacking in capacity.

8.4.3.5 Comprises objective dietary assessment, dietary analysis and tailored feedback

The data also recommended that at the start of diet intervention delivery, a baseline assessment of habitual dietary intake should be conducted to determine outcomes related to the individual's dietary needs. This is interesting as it again ties in with a keenness for objectivity and the need for evidence in the provision of a diet intervention. It also suggests clear value in individualised support and working towards individualised outcomes (idiographic approach), as opposed, or in addition to, generic outcomes (nomothetic approach), which is not a new concept in providing effective healthcare interventions (Nelson-Gray, 1996). An approach whereby a blend of both individualised and generic outcomes is supported may have merit and are aligned to patient-centred or co-produced outcome generation (Ashworth et al., 2019).

8.4.3.6 Directly supports dietary deficiency through supplementation, where appropriate

Data from both stakeholder groups suggested that the safe provision of diet supplements should be included in a dietary intervention for psychosis management. This ties in with HCPs' perceived responsibility of the duty of care that both they and services have to provide the best care to patients. If evidence indicates that there is a) a deficiency of nutrients and b) that the said deficiency may cause an individual harm, then it is important to support a correction of that deficiency as part of the care provided by services and professionals. The nature of the 'evidence' required to make that decision would fundamentally be underpinned by the evidence base on the topic and cited best practice, in addition to clear objective measurement of an individual's nutritional status. This would therefore be a core component to a diet intervention for psychosis management. HCPs also postulated that diet and the consumption of food should be considered as part of the safeguarding brief for patients, due to the potential for harm that it can have from the under or over consumption of nutrients. This would be an interesting area to explore further with stakeholders in terms of resources and specific processes required to enact that as part of diet-related interventions for psychosis management.

8.5 OUTCOMES

<u>8.5.1 Short Term</u>

The integrated findings from both groups advocates that one of the demonstrable outputs of the diet intervention for patients is a clear understanding of how food can benefit the brain and thus impact psychosis. Another desired output from the integrated findings is that patients should feel the potential for diet as a source of social contact and a source of personal achievement, empowerment and pride. This links to the view across both stakeholder groups that food is more than just a source of nutrients or a source of energy.

Another short-term output for patients is that the diet intervention should engender within patients a more positive relationship with food. Evidence of a successfully delivered intervention, in this context would include that patients are able to demonstrate the flexibility to tailor their diet to suit their own context, circumstances and preference. Examples of this for some patients and carers would be to consume beneficial foods of known provenance. A related short term output transpiring from the diet intervention, as suggested within the findings from both groups is that patients could articulate the perceived benefits of sharing food and cooking experiences with others. The additional benefit beyond the experiential enjoyment of a shared meal is that this could act as a potential motivator and as a means to enhance quality of life, through evoking memories and through the benefits associated with social interaction.

8.5.2 Medium Term

8.5.2.1 Patient behaviour change relating to diet

Following the shorter-term outcome of patients and carers increasing their knowledge and skills, the diet intervention should lead to a medium-term outcome of discernible and measurable behaviour change for patients in relation to diet.

8.5.2.2 Organisational and 'decision maker' buy-in

One of the medium-term outcomes of the delivery of the diet intervention would be a clear commitment from Commissioners of services and NHS Trusts that they value the delivery of diet intervention for psychosis management. In addition to a) granting permission for this to happen services, commissioners and organisations may b) also be willing to fund this on an ongoing basis, including the release of existing staff and/or the employment of new staff to support this.

8.6 IMPACT

The integrated data has provided detailed information to support the processes required to effectively deliver a dietary intervention. Additionally, the data also indicates potential areas of impact following delivery of the intervention (see Figure 12). One of the key impacts of delivering the diet intervention for psychosis management is a potential improvement in psychosis for patients and a potential improvement in the health of patients, more generally. This is because, if the intervention is delivered successfully, patients would have knowledge and skills that lead to sustainable, long-term changes in behaviour. An improvement in psychosis and the health of patients could lead to an improvement in their functioning and quality of life, thus reducing the burden to patients and their carers.

Another impact from the delivery of the diet intervention is that this would represent a new strand to care delivery in terms of psychosis management, which would then become embedded as a standard part of treatment for psychosis. This has the potential to impact not only in the United Kingdom, but could then be adapted in other countries. It is important to note though that for the diet intervention to be successful in other countries, it may require adaptation to align with the contextual factors considered important by psychosis patients in that country.

The impact from the intervention at an individual level is the potential for the focus of dietary intervention to shift from the effect on the physical health of those with psychosis across to psychosis management, and with the potential for tangible benefits, such as a medication sparing effect. At an organisational level, the impact of backing the development of this intervention would be professionals able to uphold a duty of care, which includes the provision of nutritious food as directed by the NHS Constitution (DHSC, 2021) and could lead to the inclusion of diet as part of safeguarding guidance. At a regional or national level, embedding the intervention may represent a culture whereby mental health has equality to physical health in terms of service provision.

8.7 ASSUMPTIONS

It must be acknowledged that the results and discussion of integrated findings from both groups, and the associated logic model (see Figure 12), are based on some fundamental assumptions. One assumption is that NHS service commissioners, providers and decision makers have sufficient interest to firstly agree to the concept of providing diet intervention for psychosis management and secondly that they are then willing to invest financial resources to facilitate the initial development and then the subsequent delivery of this.

A second assumption is that academic institutions (e.g. Universities) that provide pre-registration or post-registration healthcare curricula would be willing to support the provision, delivery and regulation of academic training and CPD related to diet intervention for psychosis management. The assumption goes beyond a willingness to include the financial and infrastructural resources required to invest in the development of such as intervention. This is a fundamental element to pursue as an early first step in the development of a diet intervention for psychosis management because the findings across both groups strongly suggest that trained professionals, with sufficient knowledge would be essential to the delivery of the intervention.

There is also a fundamental assumption that the outcome of a co-produced diet intervention would be that it was successful and thus improved psychosis symptoms and would therefore be an important part of psychosis management. This assumption is also set in the context of the systematic review findings where there was no peer-reviewed evidence of diet interventions trialled for psychosis management and no robust evidence suggesting that diet supplement interventions were effective. It will be important throughout the development and implementation phase of the diet intervention therefore to ensure that robust evaluation of the intervention is carried out to help improve and refine the intervention throughout its phases of development.

The implementation of new care interventions or pathways often require infrastructural support that may not be clearly apparent, such as Information Technology (IT) requirements from organisations, that can link to such things as recording outcomes in medical notes (Torseth and Adnanes, 2022). Likewise there is a cost to organisations to maintain and provide heat and light for buildings and facilities, such as kitchens for cooking groups. These contextual elements will be necessary for the successful delivery of a diet intervention, but may not be apparent to the HCP and Patient and Carer stakeholder groups.

8.8 EXTERNAL FACTORS

There is the potential for external factors to impact on the provision of a diet intervention for psychosis management. These factors will exist outwith the control of patients and carers, HCPs delivering the intervention and organisations associated with the development and delivery of the intervention. They include examples such as unexpected events, such as the recent Covid-19 pandemic, changes in Government, both of which may change NHS funding priorities and there is the overall stability of the NHS and mental health service provision. Likewise, there is the current cost of living crisis, which may have a direct impact on diet and the provision of food at an individual level with people having to change what they can afford to eat. All of these external factors should be considered during the development and onward delivery of a diet intervention, as strategies may be required to overcome the impact of these.

8.9 Remaining areas of Uncertainty

In addition to the external factors listed in the Logic Model (Figure 12), there remains some areas of uncertainty related to the diet intervention. One of the uncertainties following the data synthesis is clarity on the role of carers within the development and delivery of a diet intervention for psychosis management. The role of the Carer may be different at different time points throughout the psychosis journey, such as of less prominence if a patient is on the mental health ward, versus if the patient is staying at home in the community. The Carer's role may vary with individual circumstance and may therefore link to the tailoring or personalisation of the diet intervention for individuals.

A second uncertainty relates to timings. Firstly, there it is unclear how long it would take to develop a suitable diet intervention for psychosis management ready for the pilot phase of a complex intervention, as set out by the MRC (Skivington et al., 2021). Secondly, whilst there was consensus across both groups that the diet intervention should be delivered to patients across their psychosis treatment journey, it remains unclear whether this should be in discrete blocks with a clear time limit, or whether this should be part of ongoing daily or weekly psychosis care. There is heterogeneity in the duration of diet interventions aimed at boosting knowledge to improve individual's dietary habits. An example from the early literature suggested that a brief dietary intervention was sufficient to effect dietary change (Schapira et al., 1991), whilst a more recent example advocated a longer (6 month) duration (Øverby et al., 2021). This will require some consideration as part of the next stages of the development of the diet intervention for psychosis management.

8.10 Chapter Summary

This chapter has presented the integrated findings from both studies has elucidated contextual and programme theory elements required for the development and onward delivery of a diet intervention for psychosis management. The core components of the diet intervention as represented in a Logic Model (see Figure 12). These core components comprise inputs, activities related to both the development and then delivery of a diet intervention and then the expected outcomes and impact associated with delivering the diet intervention for psychosis management. Examples of these include inputs, such as competent HCPs, finance and equipment, with the expected activities relating to the development of training to boost HCP's knowledge and competence prior to them delivering the evidence-based, tailored diet intervention with a practical focus that is engaging and easy for patients to understand. The expected short-term outcomes include the successful delivery of a diet intervention with clearly defined objectives of dietary change for individuals and an increase in knowledge of both HCPs and patients and carers. Medium-term outcomes include firstly objectively measurable dietary change by patients following receipt of the intervention and secondly the potential for attitudinal change within NHS mental health services in relation to the provision of this diet intervention. The expected impact of the diet intervention for psychosis management is that it becomes formally embedded into psychosis care because it has led to an improvement in the health of patients, through an improvement in psychosis. A range of external factors that are outwith the control of those developing and delivering the intervention, such as changes in Government of future pandemics are also acknowledged in the Logic Model (Figure 12). Likewise, an articulation of key assumptions that have been made, which include key organisations and their respective individuals, such as universities and commissioners will be interesting and willing to engage and fund the development of a diet intervention for psychosis management. The narrative of this chapter has articulated these core elements of the diet intervention for psychosis management and related them to the wider literature. The final part of this chapter's narrative described some of the key uncertainties which remain following the integrated findings. These include a lack of clarity on the potential role for carers in relation to receipt of the diet intervention for psychosis management and a lack of clarity on the duration of the proposed diet intervention. The implications of the synthesised findings, with recommended next steps and a conclusion to this thesis are presented in the next chapter.

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9. RECOMMENDATIONS AND CONCLUSION

This chapter presents a summary of the outcomes of the sequential parts of this PhD inquiry and the implications of the findings, with suggested next steps. Also presented and discussed are the limitations identified within this PhD and then this chapter culminates in a conclusion.

9.1 Summary of the outcomes of the key parts of this PhD

The value provided following completion of this PhD to a) the evidence base and b) hopefully to those experiencing psychosis as part of a post-doctoral research programme is listed below:

1) Following a robust systematic review and meta-analyses of trialled diet or diet supplement interventions aimed at improving psychosis in those aged 14 - 65, it was clear that there were no interventions of suitable rigour to warrant evaluation and wider clinical implementation.
2) The findings of the systematic review suggested that study teams who had trialled diet supplements had failed to consider the acceptability and contextual factors surrounding these interventions. These factors would need to be explored as part of the development of a diet intervention.
3) The views of HCPs as a key stakeholder group were built into four themes, which in summary suggest a positive view of the concept of diet for psychosis intervention, however an increase in knowledge would be required ahead of interventional delivery within services.
4) The views of Patients and Carers as another key stakeholder group were also built into four themes and again suggest that they too perceive there to be value in providing a diet intervention for psychosis management.
5) When synthesised and converted into a pipeline logic model (Funnell and Rogers, 2011), findings from both stakeholder groups provided core elements of the diet intervention and clearly indicated that there is value in pursuing a diet intervention for psychosis management.
6) In addition to core elements of the diet intervention, there was clarity on key uncertainties and missing data, such as the views of commissioners of psychosis services and healthcare academics. Work on these areas would be the suggested next steps as part of a post-doctoral programme of study.

9.2 Implications of the synthesised findings

9.2.1 There's value in appropriately trained mental health HCPs providing a diet intervention

The first key finding from this PhD is that the concept of diet intervention for psychosis management was met positively by both HCPs and patients and carers, however it must be acknowledged that as a view it clearly stems from a position of both groups having limited knowledge or experience of diet intervention for psychosis. This may stem from the lack of published evidence of diet or diet supplement interventions for psychosis management, as evident from the systematic review conducted as part of the PhD. The development and implementation of an intervention thus needs to start from a position whereby HCPs have access to a trusted source of evidence-based information to help equip them with both the knowledge and the confidence to believe in the value of a diet intervention for psychosis management. To effect this, an accessible, evidence-based and objectively monitored source of training would be required for HCPs, which should be linked to HCP curricula.

A key uncertainty identified was who was best placed to provide the diet intervention. There was consensus between the groups that this should be delivered within NHS mental health services, however there was dissonance within the HCP group with some suggesting that there may be a role for them as qualified mental health professionals, such as nurses, yet other suggesting it requires HCPs trained in nutrition or dietetics. This may stem from anxiety fuelled by a lack of knowledge on the topic, which may be ameliorated by appropriate training. Alternatively, there may be a role for a range of professional disciplines, with multiple professional groups supporting both the development and delivery of the training and intervention materials.

9.2.2 Engagement with key decision makers, such as psychosis service commissioners

Another finding from the synthesised data was that significant resources, in terms of personnel, materials, partners, technology and venues and thus it would be naïve to think that interventions can be developed and delivered without resource. A crucial element influencing the development and onward delivery of a diet intervention for psychosis management therefore are the views of key decision makers, such as commissioners of mental health services. Their views would be fundamental to ensure that NHS Trust mental health services were supported to deliver this strand of care from a financial perspective. Following the Covid-19 pandemic, the financial situation of the NHS is far from ideal, with additional in-year cost pressures greater than the planned budgetary increase (Warner and Zaranko, 2022).

9.2.2.1 Next steps

1) To engage academic institutions that provide pre- and post-registration training to HCPs working in psychosis services. This is to see if they are interested and willing to support the development and routine delivery of dietary knowledge for psychosis training to HCPs. The willingness of academic institutions to provide this knowledge and skills-based training will be a crucial step in the development of a diet intervention for psychosis management.
2) As part of the development phases of the intervention seek the views of stakeholders, primarily HCPs, on who is keen to develop and deliver the intervention is sufficient training and organisational and professional support exists
3) Engagement with mental health service commissioners and key NHS budget holders to seek their views on the provision of a diet intervention for psychosis services would be another crucial next step in the development of a diet intervention for psychosis management. Without their support, seeking an alternative provider for the diet intervention would be required.
4) The findings of the systematic review were that there was no robust evidence of effective dietary interventions for psychosis management. A clear plan to measure the effectiveness of the diet intervention will be included throughout the development and implementation phases of the diet intervention. This will be important because there is an assumption that a co-produced diet intervention will be effective at psychosis management.

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9.2.3 A diet intervention for psychosis management should be personalised, evidence based and impart knowledge and skills

The second key finding from this PhD is that there was a wealth of data on what could constitute a high-quality dietary intervention for psychosis management, such as the need to provide opportunities for patients to acquire knowledge and skills. In line with the safe provision of a high-quality evidence-based intervention is the concept of objectively measuring change over time, aligning to existing theory, such as behaviour change and the ability to determine nutritional status and correct any deficiencies that exist. Delivery should also be mindful of individual circumstance and the impact of illness, e.g. budgets and lack of concentration and safety around cooking. In support of the provision of the intervention is the concept that irrespective of the different strands involved, there should be a unified approach in terms of delivering a consistent message. The wealth of data describing and articulating the key components, aspects, processes and values pertaining to a diet intervention has advanced the programme theory of a dietary intervention for psychosis management. Missing from the integrated findings was firstly a sense of the role of carers in receipt of the diet intervention and secondly a sense of suggested timings for a diet intervention. Potential options include it being delivered in discrete blocks or will it be integrated into the delivery of other care and happen on a daily or weekly basis.

9.2.3.1 Next steps

1) Further engagement is recommended with HCPs and Patients and Carers firstly to explore the role or level of involvement that Carers perceive they would have when patients are receiving the diet intervention and secondly, the timeframe for delivery.

9.2.4 The future development of a diet intervention for psychosis management: Post-Doctoral programme of work

The outcome of this PhD is that whilst no suitably effective diet intervention existed for psychosis management, there is a perceived value from HCPs and Patients and Carers in developing one. This PhD has also contributed evidence of key elements of programme theory necessary for the development and delivery of a diet intervention for psychosis management. There were uncertainties and areas of silence within the data, resulting in some suggested ‘next steps’ in the development of the diet intervention. These next steps indicate that further engagement work is required with key stakeholder groups, which should be expanded to include representation from academic institutions providing HCP curricula and NHS mental health service commissioners.

A practical option to address the next steps, could be to hold a workshop or consensus event, or a series of these, whereby stakeholders are invited to discuss and refine the data generated and synthesised as part of this PhD to help elucidate key uncertainties related to the design of the intervention would have merit. This proposed post-doctoral programme of work would align with the next step in the MRC's development phase (step 3), which is to consider who should be aware of the intervention (e.g. systems and organisations) and to consider the economic implications of a healthcare intervention (Skivington et al., 2021). The discussion and agreement on what is required for where would then provide greater detail on the resource requirement for each of these potential strands of intervention. Taking dietary and physiological monitoring of nutrient levels for an individual as an example, it may be the case that specialist diet recording software and an HCP trained in phlebotomy are required, complete with the necessary kit associated with extracting and analysing a blood sample. Understanding and confirming agreement on key aspects of the diet intervention at this granular level would allow a calculation of costs associated with its development and delivery.

The outcomes of a consensus event with a range of stakeholders, including academics and NHS budget holders and those who commission NHS mental health services should lead to the generation of areas of new knowledge on processes, resources and contextual factors required for an impactful diet intervention for psychosis management, which remain unknown following completion of this PhD.

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9.3 Limitations

9.3.1 Systematic Review

The systematic review and meta-analyses suffered from a lack of published evidence. The evidence that was published lacked detail in reporting particularly of key aspects such as concurrent (baseline) dietary recording and explanation of attrition rates. The sample sizes were also small giving a low overall sample for meta-analysis, with little or no information on whether the studies were sufficiently powered to detect an effect from the trialled intervention.

9.3.2 Qualitative Studies

A key limitation to the two qualitative studies was participants' lack of awareness or knowledge on the topic, which likely resulted in some of the interviews being quite short in duration. As these were exploratory studies there was no way of knowing to what extent people would have knowledge or what their views would be and thus these were important findings. Likewise, one option could have been to present potential participant with some key information on the topic, but that may have biased them towards favouring the concept of diet for psychosis management.

Acknowledgement that data quality may have been adversely affected within the Patient and Carer study for some of the interviews, because the individual's named clinician was present throughout. The individuals may not have felt they could be completely honest whilst representatives of the NHS service were present. On the other hand, it could also be argued that if they trusted the clinician that may have helped relax the patient and carer participants and then led to a freer speech and thus better quality data. It is hard to know to what extent this impacted on the data collected as part of the study.

A further potential limitation is that the interview transcripts (focus group and individual) could have been subject to member checking prior to the data analysis. The decision was taken not to subject interview transcripts to member checking because the participants may have altered their views as a result of participation in the research. It is acknowledged though that member checking the transcripts may have improved the accuracy.

9.3.3 Across the PhD

There were time delays due to the pandemic. The pandemic delayed data collection from the two qualitative studies because all non-covid research was paused by the local NHS Trust, in line with national guidance and the PhD candidate was required to forego study time to be diverted to covid-related duties. Likewise, the pandemic may have adversely impacted recruitment, particularly to the Patient and Carer study. This is due to clinicians being unable to make necessary care-based appointments with patients and carers, which of course meant there were no research appointments being made. There were also time delays due to the part-time nature of the PhD candidature. The part-time nature of the PhD meant that the research progressed relatively slowly, compared to standard research projects, which may mean that some of the PhD's findings may not be as relevant due to global changes, such as the current 40-year high for inflation and rising energy costs in the U.K.

Qualitative study participants may have self-selected to take part because they are particularly keen or open to the concept of diet and nutrition for the management of psychosis. This may not be representative of the wider sample for both HPC and patients and carers. This may be a useful area to explore as part of a further stakeholder workshop, including suggestions on the challenge of how to convince or engage those who are apathetic or resistive to the concept of a diet intervention for psychosis management.

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9.4 Conclusion

This Pragmatic, mixed-methods PhD used an explanatory sequential model (Creswell and Plano-Clark, 2017), guided by the MRC framework for the development and evaluation of complex healthcare interventions (Skivington et al., 2021) to explore the value of diet intervention for the management of psychosis. No suitable diet intervention(s) was the outcome of a systematic review and meta-analyses of the published literature, which led to the conduct of two qualitative studies with two key stakeholder groups: HCPs and Patients and Carers, where data were analysed thematically using Braun and Clarke (2006) and then reported and discussed. There were four themes constructed from the data for each of the respective studies and these suggested that whilst participants had limited knowledge on the topic, they did believe there to be value in exploring a diet intervention for psychosis management. The final part of this PhD was the integration of the findings from both qualitative studies to elucidate the key known (as evident from the findings) and unknown (as evident as areas of silence) components of the development and delivery of a diet intervention for psychosis management. The recommendation following this PhD is to continue to pursue the development of a diet intervention for psychosis management with an increased stakeholder group, which according to the integrated findings, should include NHS mental health service commissioners and representatives from Academic institutions which host HCP pre- and post-registration curricula.

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