Feasibility and Acceptability of Tailored Health Coaching Intervention to Improve Type 2 Diabetes Self-Management in Saudi Arabia: A Mixed-Methods Randomised Controlled Trial

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A thesis submitted in partial fulfilment of the requirements for the degree of Doctor of Philosophy

The University of Sheffield

School of Medicine & Population Health

Sheffield Centre for Health & Related Research (SCHARR)

July 2023

Acknowledgements

Foremost, I extend my deepest gratitude to God, who bestowed upon me the capabilities and opportunities that were essential to the successful completion of this research. Without His divine grace, my journey could not have been realised.

I express my deepest gratitude to my research supervisors, Professor Elizabeth Goyder and Dr. Samantha Caton, for their invaluable guidance throughout my academic journey. I am particularly indebted to Professor Goyder, whose prompt and insightful responses to my work played a crucial role in my progress. Their combined expertise, thorough oversight, and unwavering support have been consistent sources of inspiration and motivation. The constructive feedback and the readiness with which they addressed my queries significantly contributed to the success of my research. I wholeheartedly appreciate their generous investment in my academic development and career growth.

To my wonderful wife, Latifah, I want to express my sincere thanks for her constant support throughout the hurdles, impatience, and frustrations I encountered during this research process. Her positive encouragement during our conversations was instrumental in polishing my thoughts, and she was always swift to steer me right when I erred. I also offer my profound gratitude to my children, Nasser and Faisal, for understanding and tolerating my absence at home during the research and completion of this project. Their genuine care for my health and prayers for my success means a lot to me. Currently, we are filled with anticipation as we await the arrival of our newest family member. The eagerness is overwhelming as we mark off the days until we get to hold our cherished baby daughter, who is expected to join us on July 12th.

To my great family, thank you! My family has always supported and guided me, giving me valuable treasures, I will always cherish. A special tribute goes to my beloved mother, Hessa, whose relentless support, infinite love, and ceaseless prayers have been my stronghold.

Knowing that she always believes in me, and has been cheering me on, has fuelled my strength and inspiration to push forward.

My sincere appreciation goes to Saudi Electronic University in Saudi Arabia for their generous sponsorship, which provided me with the opportunity to pursue my postgraduate studies. I also extend my gratitude to the Public Health Department at the University for their constant support and guidance throughout the course of my PhD journey.

Abstract

Background: Around a third of Saudi Arabia's people have been diagnosed with Type 2 diabetes, a condition best managed through a healthy lifestyle. Personalised health coaching, a strategy known for assisting individuals in overcoming challenges to adopt healthy behaviours, has not yet been applied in the country.

Aims: This research aims to explore the feasibility and acceptability of tailored health coaching in Saudi Arabia, which could aid those with Type 2 diabetes in more effectively managing their conditions.

Methods: Using a mixed-methods approach, this research involved a randomised controlled trial with 30 adults who have Type 2 diabetes. They were randomly allocated into either the intervention or control arm for 12 weeks. The Capability, Opportunity, Motivation, and Behaviour framework was used to guide the intervention implementation along with the Behaviour Change Techniques Taxonomy version 1. The primary goal was to assess the suitability and duration of the intervention, recruitment, retention, and completion rates. The secondary outcome focused on the preliminary efficacy of the health coaching measured by the glycaemic index, blood pressure, body mass index, waist circumference, weight, patient self-efficacy, and diabetes self-management.

Results: The results showed high rates of eligibility, recruitment, and retention (a screening rate of 90%, a recruiting rate of 79%, and a retention rate of 97%). Notable improvements were observed in the health coaching group across five outcomes: HbA1c, BMI, waist circumference, patient self-efficacy, and diabetes self-care. The participants were satisfied with the intervention and requested its expansion.

Conclusion: The findings demonstrated positive outcomes, supporting the need for a larger randomised controlled trial to evaluate the efficacy of health coaching in improving diabetes self-management among individuals with Type 2 diabetes in Saudi Arabia.

Table of Contents

Contents

Acknowledgements **2**

Abstract **4**

Table of Contents **6**

List of Tables **10**

List of Figures **11**

List of Appendices **12**

List of Abbreviations **13**

Authorship Statement **15**

CHAPTER 1: Introduction ***1***

1.1 Overview **1**

1.2 Introduction **1**

1.3 Thesis outline: **2**

1.3.1 Chapter 2: Background 2

1.3.2 Chapter 3: Systematic Review and Meta-Analysis 2

1.3.3 Chapter 4: Methods 2

1.3.4 Chapter 5: Results 3

1.3.5 Chapter 6: Discussion 3

1.3.6 Chapter 7: Conclusion 3

CHAPTER 2: Background ***4***

SECTION 2.1: The research problem **4**

2.1.1 The research problem 4

2.1.2 Introduction: Saudi Arabia 7

2.1.3 Vision 2030 and Healthcare 8

SECTION 2.2: Type 2 Diabetes **9**

2.2.1 Incidence and Prevalence: 9

2.2.2 Pathology and Aetiology of T2DM in SA 11

2.2.3 T2DM Humanistic Burden 14

SECTION 2.3: Usual Care **16**

2.3.1 Diabetes usual care 16

2.3.2 Recent Changes to diabetes management in SA 17

2.3.3 Lifestyle intervention as a priority to address the T2DM 18

2.3.4 Need for Adopting a healthy lifestyle 19

2.4 Behaviour Change Wheel as a diagnostic tool for behaviour change interventions **20**

2.4.1 Barriers to Adopting a healthy lifestyle for Saudi Patients with T2DM **21**

2.4.1.1 Environmental Context and Resources (OPPORTUNITY- PHYSICAL) 23

2.4.1.2 Social influence (OPPORTUNITY-SOCIAL) 25

2.4.1.3 Knowledge (CAPABILITY-PSYCHOLOGICAL) 27

2.4.1.4 Physical skills (CAPABILITY-PHYSICAL) 30

2.4.1.5 Beliefs about capabilities (MOTIVATION-REFECTIVE) 30

2.4.1.6 Beliefs about consequences (MOTIVATION-REFLECTIVE) 31

2.4.2 Identification of intervention behaviour targets **31**
2.4.3 Identification of intervention functions and behaviour change techniques (BCTs) **32**
SECTION 2.5: Health Coaching **35**
2.5.1 Definitions and Theoretical Basis 35
2.5.1.1 Health belief model (HBM) 36
2.5.1.2 Transtheoretical Model (stages of change) 37
2.5.1.3 Self-determination Theory 37
2.5.1.4 Motivational Interviewing 37
2.5.1.5 Cognitive Behaviour Therapy (CBT) 38
2.5.2 Health coaching growing in popularity **38**
2.5.3 Health coaching as a promising approach to T2DM management in SA **40**
2.5.4 Health coaching content **41**
SECTION 2.6: Aims and Objectives **42**
2.6.1 Overall research aim 42
2.6.2 Research objectives: 42
CHAPTER 3: Systematic Review and Meta-Analysis ***44***
3.1 Chapter overview 44
3.2 Authors' Contributions 45
3.3 Publication reference 46
CHAPTER 4: METHODS ***71***
4.1 Introduction **71**
4.2 Section I **72**
4.2.1 The rationale for conducting a feasibility study before a definitive trial of health coaching in SA 72
4.2.2: Research philosophy 75
4.2.3 Research approaches: 76
4.2.4 The rationale for selecting mixed methods design: 77
4.2.5 Research design: 77
4.2.6 Research quality: 78
4.3 Section II **78**
4.3.1 Publication reference 78
4.3.2 Authors Contributions 79
4.3.3 Supplementary methods (for trial protocol) 107
4.3.3.1 Use of Motivational Interviewing and Transtheoretical Model 107
4.3.3.2 Questionnaires 107
4.3.3.3Summary of Diabetes Self-Care Activities (SDSCA) scale 107
4.3.3.4 Self-efficacy Scale for Diabetes 108
4.3.3.5 Likert-Scale Satisfaction Questionnaire 109
4.3.3.6 Qualitative data 110
4.3.3.7 Focus Groups 110
4.3.3.8 Interviews 111
4.3.3.9 Field notes and session recordings 111
4.3.3.10 Thematic analysis 112
4.3.3.11 Statistical analysis 113
4.3.3.12 Integration of qualitative and quantitative data 115
CHAPTER 5: Results ***116***
5.1 Quantitative Results **116**
5.1.1 Feasibility outcomes 116
5.1.2 Acceptability of the intervention 148
5.1.2.1 Preliminary effects of the intervention 151
5.1.2.1.1 Glycosylated haemoglobin (HbA1c) 151
5.1.2.2 Secondary outcomes 153
5.1.2.2.1 Mean Arterial Pressure (MAP) 153

5.1.2.2.2 Weight 153
5.1.2.2.3 BMI 153
5.1.2.2.4 Waist Circumference 154
5.1.2.2.5 Patients' self-efficacy questionnaire 158
5.1.2.2.6 Diabetes Self-Care Activity 160

5.2 Qualitative Results 162
5.2.1 Introduction 162
5.2.2 Results of interviews and focus groups with participants and health coaches 162
5.2.3 Thematic analysis 164
5.2.4 Integration of qualitative and quantitative results 193
5.2.5 Conclusion 202

CHAPTER 6: Discussion 204

6.1 Introduction 204

6.2 Feasibility of proceeding to a larger-scale study 204

6.3 Intervention mechanism and participants' experience 208

6.4 Sample size estimation for the main RCT 212

6.5 Acceptability and usability of the intervention 213

6.6 Satisfaction with the intervention 215

6.7 Improvement opportunities in the future definitive RCT 216

CHAPTER 7: Thesis Conclusion and Recommendations 218

7.1 Introduction 218

7.2 Original contribution to knowledge 218

7.3 Implications for Trial Methods 220

7.4 Implications of the feasibility study for the development of health coaching for patients with chronic disease, including diabetes 221

7.5 Implication for policy and practice 222

5.6 General recommendations for future research and the definitive trial 224

7.7 Strengths and limitations of the study 225

7.8 Implications of the COVID-19 pandemic on this research 227

7.9 Planned dissemination 230

7.10 Conclusion 232

References 234

Appendices 244

Appendix 1: The APEASE criteria 245

Appendix 2: Summary of Diabetes Self Care Activity (SDSCA) 246

Appendix 3: Self-efficacy Scale for Diabetes 248

Appendix 4 : Likert-Scale Satisfaction Questionnaire 249

Appendix 5: Permission to use Likert-scale Satisfaction Questionnaire 251

Appendix 6: Study questionnaire (English Version) 252

Appendix 7 : Study questionnaire (Arabic Version) 257

Appendix 8: Focus group questions guidance (Health coaches) 267

Appendix 9: Interview Guide questions 272

Appendix 10: Health coaching intervention curriculum 275

Appendix 11: Participants' mean differences in each group at baseline and endpoint for patients' self-efficacy questionnaire..... 307

Appendix 12: Participants' mean differences in each group at baseline and endpoint for diabetes self-care activity questionnaire..... 309

Appendix 13: The study's ethical approval and participation consent form..... 311

Appendix 14: Email about systematic review from NHS Trust..... 319

List of Tables

Table 2-1: Description of the selected TDF domains to identify what needs to be changed .. 34
Table 2-2: ICF Core Coaching Competencies [102] 36
Table 5-1: Summary of the participants' demographic characteristics 122
Table 5-2: Time spent in each coaching session 124
Table 5-3: Feasibility Measurements and Predetermined progression criteria 126
Table 5-4: Coaching sessions tracking schedule for each participant 128
Table 5-5: Defined problems in behavioural terms 130
Table 5-6: Behaviour target 1 (Decrease carbohydrate intake for each meal) 132
Table 5-7: Behaviour target 2 (Use unsaturated fats where possible ((avoid saturated fats)) 137
Table 5-8: Behaviour target 3 (Do exercise for 30 min, five days on a weekly basis) 140
Table 5-9: Behaviour target 4 (Monitor waist circumference, maintain it below (80 cm for women and 94 cm for men) 143
Table 5-10: BCTs used in the interventions 144
Table 5-11: Participant Ratings of Health Coaching on a 10-Point Likert Scale (intervention group only) 149
Table 5-12: Frequency and percent of each participant's response 150
Table 5-13: HbA1c means and SDs for both groups at the study baseline and endpoint 152
Table 5-14: HbA1c outcome difference, taking into account the baseline value 152
Table 5-15: Groups means and SDs at study baseline and endpoint 154
Table 5-16: Secondary outcomes mean differences, taking into account the baseline value 155
Table 5-17: Average participants' responses for both groups at baseline 159
Table 5-18: Average participants' responses for both groups at the endpoint 160
Table 5-19: Participants' responses average for the diabetes self-care activity questionnaire for both groups at baseline 161
Table 5-20:Participants' responses average for the diabetes self-care activity questionnaire for both groups at the endpoint 161
Table 5-21: Participants' demographic characteristics 164
Table 5-22: Joint display table 194

List of Figures

Figure 2-1: Saudi Arabia [29] 9
Figure 2-2: Behaviour Change Wheel Framework [1] 21
Figure 4-1: Thematic analysis (Adapted from Braun & Clarke, 2006) [175] 113
Figure 5-1: CONSORT Flow Diagram of the health coaching RCT[2] 119
Figure 5-2:HbA1c level changes for each participant in each group from the study baseline to the endpoint 152
Figure 5-3: MAP changes for each participant in each group from the study baseline to the endpoint 156
Figure 5-4: Weight changes for each participant in each group from the study baseline to the endpoint 156
Figure 5-5: BMI changes for each participant in each group from the study baseline to the endpoint 157
Figure 5-6: Waist circumference changes for each participant in each group from the study baseline to the endpoint 158
Figure 5-7: Thematic analysis map 166

List of Appendices

Appendix 1: The APEASE criteria

Appendix 2: Summary of Diabetes Self Care Activity (SDSCA) 12-items

Appendix 3: Self-efficacy Scale for Diabetes 8-items

Appendix 4 : Likert-Scale Satisfaction Questionnaire, 14-items

Appendix 5 : Request permission to use Likert-Scale Satisfaction Questionnaire, 14-items

Appendix 6 : Study questionnaire (English Version)

Appendix 7 : Study questionnaire (Arabic Version)

Appendix 8: Focus group questions guidance (Health coaches)

Appendix 9: Interview guide questions

Appendix 10: Health coaching intervention curriculum

Appendix 11: Participants' mean differences in each group at baseline and endpoint for patients' self-efficacy questionnaire

Appendix 12: Participants' mean differences in each group at baseline and endpoint for diabetes self-care activity questionnaire

Appendix 13: The study's ethical approval and participation consent form

Appendix 14: Email about systematic review from NHS Trust

List of Abbreviations

ADA: American Diabetes Association

APEASE: Affordability, Practicality, Effectiveness and Cost-effectiveness, Acceptability, Side-effects/safety, and Equity

BCT: Behaviour Change Techniques

BCTTv1: Behaviour Change Techniques Taxonomy Version 1

BCW: Behaviour Change Wheel

BMI: Body Mass Index

CBC: Centre for Behaviour Change

CBT: Cognitive Behaviour Therapy

CDC: Centre for Disease Control and Prevention

COM-B: Capability (C), Opportunity (O), Motivation (M) and Behaviour (B)

CONSORT: Consolidated Standards for Reporting of Trials

DPP: Diabetes Prevention Programme

FPG: Fasting Plasma Glucose

GDP: Gross Domestic Product

HbA1c: Glycated Haemoglobin

HBM: Health Belief Model

HRQoL: Health-Related Quality of Life

ICF: International Coach Federation

IGT: Impaired Glucose Tolerance

KFMC: King Fahad Medical City

MI: Motivational Interviewing

MoH: Ministry of Health

MRC: Medical Research Council

OGTT: Oral Glucose Tolerance Test

RCT: Randomised Controlled Trial

SA : Saudi Arabia

SD : Standard Deviation

SDSCA: Summary of Diabetes Self-Care Activity

SR: Saudi Riyal

T2DM: Type 2 Diabetes Mellitus

TDF: Theoretical Domains Framework

TTM: Transtheoretical Model

WHO: World Health Organisation

Authorship Statement

Chapters 3, 4, and 5 of this thesis contain either published papers or papers that are currently being reviewed by peers. Chapter 3 contains one paper that has already been published in BMC Public Health. Chapter 4 includes a single paper that has been published in the International Journal of Environmental Research and Public Health. Each chapter begins with a brief summary of the author's contribution and its relevance. The references for these papers can be found listed below.

Chapter 3:

Almulhim AN, Hartley H, Norman P, Caton SJ, Doğru OC, Goyder E. Behavioural Change Techniques in Health Coaching-Based Interventions for Type 2 Diabetes: A Systematic Review and Meta-Analysis. BMC Public Health. 2023 Dec;23(1):1-21.

https://doi.org/10.1186/s12889-022-14874-3

Chapter 4:

Almulhim, A.N.; Goyder, E.; Caton, S.J. Assessing the Feasibility and Acceptability of Health Coaching as a New Diabetes Management Approach for the People with Type 2 Diabetes in SA: A Protocol for a Mixed Methods Feasibility Study. Int. J. Environ. Res. Public Health 2022, 19, 15089. https://doi.org/10.3390/ijerph192215089

Thesis Abstract submitted to The Lancet (to present at the UK Public Health Science conference, London, November 2023)

Almulhim A.N, Alhowaish A, Madani A, AlQaddan M, Samantha J. Caton SJ, Goyder E. Feasibility and Acceptability of Tailored Health Coaching for Type 2 Diabetes Management in SA: A Mixed-Methods Pragmatic Randomised Controlled Trial

CHAPTER 1: Introduction

1.1 Overview

This chapter provides an overview of the thesis. It also sets out the structure of this thesis presented at the end of this chapter.

1.2 Introduction

Over the last few years, Saudi Arabia (SA) has experienced significant changes, including shifts in demographics and economics. These changes have had an impact on the population's lifestyle, leading to less healthy diet choices and decreased physical activity. As a result, chronic diseases such as type 2 diabetes mellitus (T2DM) have become very common in the country. Diabetes affects around one-third of the Saudi population [3]. The significance of adopting healthy lifestyle behaviour to address the problem of diabetes is well-documented. Many healthcare systems have acknowledged the significance of shifting the current way of addressing chronic diseases to a holistic approach that combines psychological and behavioural interventions to enable individuals to modify unhealthy lifestyles at an early stage to avoid future complications [4].

Health coaching is a new approach that helps clients gain essential skills to adopt healthy behaviour and effectively manage their conditions. It has been applied and recognised as a promising method in different countries to enable T2DM patients to control the disease. Although there are encouraging outcomes from health coaching interventions, its content is still unclear to ensure effective replication, especially in different contexts like SA. For this reason, this thesis seeks to understand the content of health coaching by identifying active

ingredients, adapting it to fit the Saudi context, and exploring its feasibility and acceptability to the population.

1.3 Thesis outline:

1.3.1 Chapter 2: Background

This chapter consists of four main sections, beginning with the epidemiology of diabetes, which includes its incidence, prevalence, aetiology, pathology, and humanistic and economic impacts. Following this, a section describes the standard care for diabetes in SA, highlighting the importance of addressing lifestyle factors to help T2DM patients and the potential barriers that prevent them from adopting healthier lifestyles. The third section introduces the Capability, Opportunity, Motivation, and Behaviour framework (COM-B) as the theoretical basis for exploring how health coaching could be tailored to address Type 2 diabetes in the Saudi context. At the end of this chapter, the research aims, and objectives are presented, providing a roadmap for carrying out the research activities.

1.3.2 Chapter 3: Systematic Review and Meta-Analysis

This chapter presents a systematic review that aims to address some of the identified limitations in previous health coaching literature syntheses and to identify unanswered questions about the effectiveness and implementation of health coaching as an intervention for patients with Type 2 diabetes. Additionally, it explores the use of behaviour change techniques (BCTs) in previous health coaching interventions, which were employed to shape the intervention described in Chapter 4.

1.3.3 Chapter 4: Methods

This chapter outlines the research philosophy, epistemological assumptions, and methodological approach used in this thesis, including the research design, ethical approval for

conducting the study, and detailed information about the tools utilised for data collection using both qualitative and quantitative methods.

1.3.4 Chapter 5: Results

The findings of both the qualitative and quantitative data are presented in this chapter. It also explains how the research findings were integrated to further explore explanations for the results.

1.3.5 Chapter 6: Discussion

The key findings from the previous chapter are discussed in this chapter and connected to the broader body of literature.

1.3.6 Chapter 7: Conclusion

This chapter concludes the thesis by summarising the main findings and making some recommendations for future research and the larger health coaching trial.

CHAPTER 2: Background

This chapter consists of five sections that present the research background and the rationale for the proposed study. Section 2.1 highlights the research problem and gives a brief introduction to SA. Section 2.2 discusses the epidemiology of T2DM globally and in SA as well. Section 2.3 provides related information about the current diabetes care in SA and the challenges people face when adopting a healthy lifestyle. In this section, further details are illustrated about the use of the COM-B model and Theoretical Domains Framework (TDF). Section 2.4 reviews the barriers that stand in the way of replicating health coaching in a different context and how the thesis attempts to address this gap. Section 2.5 provides definitions of health coaching and its theoretical basis. At the end of this chapter, Section 2.6 presents the research's overall aim and objectives.

SECTION 2.1: The research problem

2.1.1 The research problem

Diabetes is a widespread chronic disease that poses a real worldwide health threat. It is among the top leading causes of death globally[5]. World Health Organization (WHO) has classified diabetes as the 7th direct leading cause of death around the world, linked with an estimated 1.6 million deaths in 2016. In 1980, 4.7% of adults over 18 had diabetes, but the percentage nearly doubled to 8.5% by 2014[6]. There was a remarkable rise in cases in 2014; the total number of diabetics increased from 108 million in 1980 to 422 million[7]. Diabetes and its related health issues, such as cardiovascular disease, stroke, and kidney disease, cause most deaths in countries with middle and low-incomes[7].

T2DM is becoming increasingly prominent among chronic diseases that are rapidly emerging as significant public health concerns. T2DM contributes to reducing life expectancy by 5-10 years, especially in the middle-aged [8]. Key contributors to T2DM include high body mass index (BMI) and inactive lifestyles[9]. If not properly managed, diabetes can trigger a plethora of serious health complications, ranging from heart and brain diseases to issues related to vision and hearing, kidney dysfunction, nerve degradation, and even the necessity for amputations. Additionally, it can cause complications with oral health and feet[10]. It's noteworthy that adults living with diabetes are two to three times more susceptible to heart-related issues and strokes. Furthermore, diabetes has negative repercussions on social life, economic status, and healthcare services[5]. Since diabetes is a preventable disease closely linked to and influenced by lifestyle, self-management serves as an ideal approach for its effective management[5]. It is worth mentioning that lifestyle interventions seem to be just as effective as medications when it comes to diabetes management[7].

SA is among the world's highest-income countries and has the largest population in the Middle Eastern region[11]. The recent tremendous changes in the country have led to a huge impact on the population's daily lifestyle. The country is witnessing accelerating rates of different chronic diseases, especially T2DM. SA ranks third worldwide for T2DM incidence among its citizens [12]. Around one-third (32.8%) of the Saudi population is diabetic, and projections estimate that the prevalence of this disease could escalate to 45.36% by 2030 [6]. A recent study revealed that a significant majority (85.1%) of Saudi T2DM patients struggle to manage the condition effectively[13]. Furthermore, about 28% of the Saudi population with T2DM lacks adequate knowledge regarding measures to prevent and manage the condition [14].

Despite numerous national programmes and initiatives, SA's healthcare system is still struggling to address the high rate challenge of T2DM. Research conducted in the country has shown that T2DM management is not as effective as it should be [15]. Current efforts are

primarily focused on raising awareness; however, patients continue to find it challenging to adopt a healthy diet and lifestyle to properly manage their condition. Many studies have demonstrated that embracing a healthy diet and lifestyle empowers patients to take control of their diabetes[16].

As individual behaviour and lifestyle play a critical role in managing T2DM, patients themselves may need to play an active role. To support patients' involvement in managing their condition, it is crucial to understand their needs and enhance their skills to manage their condition. However, healthcare professionals often struggle with time limitations during primary care appointments, which usually last only about 10-15 minutes[17]. Consequently, patients may experience feelings of negativity, overwhelm, and frustration in response to short appointments or receiving insufficient support to manage their condition. Bridging this gap requires cost-effective interventions that give heed to patients' needs and support them in tackling potential barriers.

Developing patients' self-management skills is crucial for delaying or reducing the risk of the development of T2DM and its related complications. By making healthier lifestyle behaviour choices, patients can significantly reduce the occurrence of chronic conditions associated with T2DM by 75% or more [18]. Self-management interventions can help people control and manage their T2DM [19]. Globally, the treatment of diabetes in healthcare systems has undergone a shift in focus towards the patient's individual needs, which differs from previous methods. The new approach centres on the patient, promoting a more personalised approach to care [5 20].

Health coaching that focuses on the individual client is a multi-disciplinary approach that incorporates different theories of behaviour change, such as Motivational interviewing and Transtheoretical model [21]. This method has gained popularity in health promotion and has shown promising results[4]. While health coaching has been a relatively recent addition to Saudi

healthcare systems[22], particularly for weight loss in primary care settings, this personalised intervention has been effective in improving diabetes self-management in various contexts [4 23]. Although it has mainly been used to enable patients with chronic diseases to manage their conditions effectively, the applicability of health coaching for promoting healthy behaviours among individuals with T2DM remains unexplored in the Saudi context. Therefore, this thesis aims to address this existing gap by investigating the feasibility and acceptability of health coaching within the Saudi population, which could provide valuable insights for a future full-scale trial.

2.1.2 Introduction: Saudi Arabia

This section briefly highlights epidemiologic diabetes-related facts in SA, where the study will take place. SA, positioned in Asia's southwest on the Arabian Peninsula (see Figure 2.1), is the Middle East's biggest country. It's home to an estimated 34,218,169 people, with an average yearly population increase of 2.4% [24]. The discovery of oil in 1925 was a turning point in SA's history, which has led to a dramatic increase in the country's wealth, as reflected in its Gross Domestic Product (GDP). The socio-economic development of the Saudi population has contributed to changes in the daily lifestyle which, as a result, affected various aspects of people's lives.

SA has witnessed vast social, demographical (urbanisation), and cultural changes caused by economic evolution. This has led to a huge epidemiological transition where the rate of infectious disease declines and is accompanied by an increasing prevalence of lifestyle-related illness [25]. Physical activity and people's diets have been dramatically impacted due to the economic revolution. Physical inactivity and an unhealthy diet play a significant role in accelerating the risk of T2DM and other chronic diseases in SA.

Islamic culture plays a significant role in shaping people's lifestyles. Not only does Islam influence the lives of the Saudi population, but it also has a large impact on government policies. Islamic culture greatly impacts different aspects of Saudi citizens' lives and how people interact with each other, especially within families and in how parents raise their children. Hence, people have huge respect for and compliance with Islam's unwritten cultural norms.

For example, individualism is uncommon in Saudi society; rather, Saudi society tends to be collectivist. Consequently, people in SA are mostly born into large extended families that provide them with a sense of protection in exchange for loyalty[26]. People tend to place a strong emphasis on belonging to a particular group and sharing common views. Therefore, it is crucial to consider and understand collectivist societies such as the SA, especially when applying new tailored programmes or interventions.

2.1.3 Vision 2030 and Healthcare

On April 25th, 2016, SA announced its first national vision: Vision 2030. This initiative intends to reorganise the country and prepare it for its future. Vision 2030 is considered a significant revolution aiming to improve different crucial aspects, including the healthcare system. It is the most comprehensive vision in SA's history [27]. Through Vision 2030, SA aims to raise health outcome levels by implementing its "Quality of Life" initiative's programmes. The goal is to increase life expectancy by six years, from 74 to 80, by 2030[27]. Accordingly, the Ministry of Health (MoH) has undertaken various initiatives and started many programmes to achieve these planned improvements and goals by 2030. The Saudi Centre for Disease Control and Prevention (CDC) has made a strategic endeavour to activate and enhance efforts to reduce the burden of chronic diseases[28]. T2DM is at the forefront of the diseases that will be targeted through these initiatives and programmes due to its high prevalence in the country. The CDC

is directly monitoring, following up, and adopting all means and procedures to prevent the spread of T2DM and enhance public health within 40 initiatives approved by the MoH within the framework of Vision 2030[28]. These initiatives aim to create an administrative and technical reference to unify efforts in the field of health promotion to predict and control chronic diseases. This will be followed by enacting public health laws, monitoring, measuring, and evaluating population health to plan new public health policies and programmes [28].

Figure 2-1: Saudi Arabia [29]

SECTION 2.2: Type 2 Diabetes

2.2.1 Incidence and Prevalence:

T2DM is a chronic disease primarily associated with lifestyle factors, impacting various facets of an individual's life, including physical, psychological, and social well-being. It exacerbates health conditions by raising the likelihood of concurrent illnesses. For example, among people with coronary heart disease, T2DM is a leading cause of death [30]. The persistent increase in T2DM prevalence proves challenging, largely due to lifestyle modifications resulting from economic advancements over the past four decades[9].

T2DM can be diagnosed through several methods, including Glycated haemoglobin (HbA1c), Fasting Plasma Glucose (FPG), and Oral Glucose Tolerance Test (OGTT). The most commonly used test recommended by the International Expert Committee to diagnose diabetes is HbA1c [31]. According to ADA (2021), when the HbA1c level reaches 6.5% or more, it means that a patient is diagnosed with diabetes. A level of 6.4% to 5.7% indicates a patient is pre-diabetic. The healthy normal level of HbA1c is less than 5.7% [32].

T2DM is becoming increasingly common worldwide, with Saudi Arabia experiencing a particularly concerning trend [33]. The country has one of the highest rates of T2DM, which has become the most widespread chronic illness in Saudi Arabia[33]. In 2017, a report from the WHO indicated that Saudi Arabia had the second-highest rates of T2DM in the Middle East and ranked seventh worldwide[30]. In addition, the prevalence rate of T2DM has increased by ten times over the past three decades in SA[5], making up about 95% of all diagnosed diabetes cases[10]. Currently, about 3 million people in SA have pre-diabetes, and 7 million have T2DM [34]. Recent research indicates that approximately 30% of the Saudi population has T2DM, and the prevalence rate is higher among older people [3].

For men and women, the prevalence of T2DM is projected to rise by 0.8 percent and 0.6 percent each year, respectively [35]. People over the age of 60 are most affected by T2DM in Saudi Arabia. T2DM is more prevalent among women than men and people with higher BMI [3]. Due

to factors like the growing rates of obesity, an ageing population, changing lifestyles, and less healthy diets, the burden of this chronic disease is likely to increase in the future [36].

2.2.2 Pathology and Aetiology of T2DM in SA

Diabetes occurs when the body stops producing insulin or reacts ineffectively to the secreted insulin[37]. Type 1 diabetes (T1DM) is characterized by the lack of insulin production that necessitates the daily control of insulin. Type 2 diabetes results when insulin becomes ineffective at regulating blood-sugar levels [38]. T2DM is a condition that occurs when the body's cells have a decreased sensitivity to the insulin produced by the pancreas' β-cells with the impaired balancing of hepatic glucose. As a result, the function of β-cell gradually declines and finally leads to a complete failure of β -cell [39].

T2DM directly contributes to worsening patients' health by increasing the risk of developing complications. Cardiovascular, micro/macrovascular diseases, neuropathy, renal failure, and foot problems are serious diabetes-related illnesses which affect various aspects of people's lives [13]. About 40.3% of T2DM patients may not be aware that they have diabetes [40]. Weight loss, slow-healing wounds, numbness, thirst, constant hunger, excessive excretion of urine, vision problems, and fatigue are some of the symptoms seen in those with T2DM. In the past, T2DM was generally only diagnosed in adults, but today it also affects children[5].

The root causes of SA's ever-growing prevalence of T2DM are increased urbanisation, economic development, increasingly sedentary lifestyles, and rising obesity which negatively impacts the majority of peoples' lifestyles. These lifestyle changes have resulted in widespread sedentary behaviours and physical inactivity among Saudis [9]. The elevated rate of T2DM in SA is linked to the high prevalence of obesity as a result of rapid urbanisation, which led to the adoption of a modern western diet and an increase in physical inactivity [41]. This is also supported by Aljohani (2011), who reports that the risk factors for T2DM among Saudi

nationals include obesity, excessive weight, unhealthy diet, and a lack of physical activities due to sedentary lifestyles[42]. This behaviour has impacted health and contributed to the rising rate of lifestyle-related diseases, including obesity, coronary artery diseases, hypertension, and T2DM [33 43 44].

The risk of developing T2DM can be accelerated by lifestyle behaviours that can be modified, such as physical inactivity and unhealthy dietary habits[45]. In addition to pharmacological care, interventions that incorporate changes in lifestyle can reduce the progression of T2DM[46]. Those who are not physically active, overweight or obese are more likely to develop T2DM [47]. T2DM is often considered a significant health risk associated with obesity[39],with approximately 80%-90% of individuals with T2DM being obese. [48]. In Saudi Arabia, a high percentage of the population remains physically inactive [16], with about 35.6% obese and 68.2% overweight[5]. Given these alarming statistics, there's a pressing need for effective strategies that encourage healthier behaviours, aiming to reduce the increased prevalence of T2DM in the country.

2.2.2.1 Physical inactivity in Saudi population

Inactive lifestyles in SA are presenting a big challenge considering the fact that more than half of the population (58.5%) are inactive[5]. The impact of physical inactivity is not limited to diabetes but also increase the risk of other chronic diseases. According to a Saudi national survey, 96.1% of the 17395 males and females aged between 30 to 70 years have physically inactive lifestyles [49]. A recent Saudi study has found that 60.1% of men and 72.9% of women are physically inactive[50]. Moreover, 51% of Saudi adults are overweight or obese [49]. SA has one of the highest levels of sedentarism globally, with a high-calorie diet intake that has led to an increase in the rate of obesity, T2DM, and heart diseases [51]. In 2013, the direct and indirect cost of physical inactivity was about 1.71 % of the total cost of health care in the country [52]. A

recent systematic review demonstrated that 18% of the burden of chronic diseases in SA could be avoided by being physically active[16]. Different obstacles, such as social and environmental conditions, can make it challenging for people to exercise; for example, not having safe places to walk or bad weather.

2.2.2.2 Dietary risk factors in the Saudi population

Dietary customs have been greatly impacted by the socioeconomic transition. This was a major factor driving changes in Saudi dietary behaviours, which has gradually moved to become more westernized with the availability of fast food and processed food. The widespread availability of restaurants, especially fast-food restaurants, and the coinciding increase in population income, has led to a remarkable change in daily eating behaviour. This nutritional transition has been identified as driving the increases in several health issues, such as obesity and T2DM, among other lifestyle-linked chronic diseases that have been recently observed among the Saudi population[53].

Moreover, the Saudi population mostly tends to rely on traditional food consumption, including a high preference for carbohydrates such as dates and breads[54]. The majority of daily food consumed in SA contains high levels of carbohydrates, added sugar, and fat with low levels of protein and fibre. Rice, pasta, bread, desserts, hydrogenated oils, and different types of dates are part of the daily diet for many Saudi people. Technology like new food delivery apps (such as Uber Eats) also contributes to altering people's dietary customs, especially for children, by increasing the level of fast-food consumption due to ease of access. This leads to an increased intake of high-calorie carbohydrates and sugar, which negatively impacts the glycaemic index. Therefore, younger generations are at high risk of developing chronic diseases such as T2DM by adopting unhealthy dietary patterns [53].

2.2.3 T2DM Humanistic Burden

The effect of diabetes is not only limited to the patient's health but also has significantly wider impacts on the patient and their caregivers, referred to as the "humanistic burden". T2DM leads to negative effects on social and economic aspects, including the patient's quality of life. It contributes to placing an additional burden on individuals who suffer from T2DM, their families, communities, societies, and the entire system of healthcare. The social and economic cost of diabetes increases with the development of other complications as a comorbidity. People suffering from diabetes are frequent users of primary healthcare as well as hospital services; on average, four days more in comparison to other patients without T2DM [55]. As a result, those with T2DM contribute to an additional load and demand on public health services, thus raising the ultimate expenditure on the healthcare system. As Hex et al. (2012) point out, T2DM causes direct costs to health services involving the treatment of the condition and its associated complications, as well as indirect costs in the form of social and productivity costs[56].

It has been noted that the Saudi governmental expenditure on the health sector has gradually increased as the MoH's budget was elevated sixty-fold: amounting to $3.2 billion in 1998, accounting for 6.2% of the national budget [57]. The healthcare budget was Seventy-five billion, which accounted for 15.6% of the total country expenditure in 2019 [57]. The Saudi government is continually increasing its average expenditure on healthcare systems in response to the rising demand for healthcare services.

The overall cost of treating the illnesses related to T2DM, including blindness, heart attack, and stroke, has increased to $245 billion, with direct medical costs of about USD 176 billion [58]. The Saudi healthcare expenditures on T2DM are dramatically increasing, so diabetic patients are ten times ($3,686 vs $380, about 21% of the overall healthcare budget) in treatment cost compared to non-diabetic [59]. Diabetes treatment directly costs the healthcare system in SA

about 13.9%, equal to 25 billion Saudi Riyal (SR) of the total healthcare budget [60]. The expected cost of treating diabetes in SA is predicted to surpass $0.87 billion, excluding the indirect expenditures resulting from health-related issues in the population, such as reduced work productivity, frequent absences from work, unemployment due to health complications, and so forth [61].

Living with diabetes can be stressful for many patients and affects various aspects of their lives. A link between the severity of T2DM and low quality of life has been shown in several studies [62]. Anxiety about managing the condition and fear of future diabetes-related complications could lead patients to be depressed and hence lose the productivity needed for maintaining a quality of life.

The burden of T2DM may also extend beyond the patient, significantly affecting their close social network, like families [63]. Having T2DM may cause family-related issues, including anxiety and emotional stress concerning the health of the person with the illness. In certain situations, families might assume the caregiving responsibilities for a family member with diabetes. This could lead to limitations on some activities, as they could potentially worsen the patient's health. Such constraints could affect family dynamics or relationships and induce emotional strain. As a result, patients' quality of life may be affected. A recent study has demonstrated a moderate level of health-related QoL (HRQoL) due to the uncomfortable condition that Saudi patients live with T2DM [62].

The nation's national healthcare system's capacity to respond to T2DM lags behind its relatively rich socio-economic status. Increasing evidence on the economic, health and social costs of treating diabetes disease in SA has made it imperative to move forward in assessing its chronic disease burden. The accelerating rate of T2DM should not be ignored as it continues to drain the healthcare budget and negatively impact patients' productivity and quality of life.

SECTION 2.3: Usual Care

2.3.1 Diabetes usual care

People with T2DM in SA are treated and managed at two levels of secondary and tertiary healthcare. These levels include health services provided by medical specialists and specialised consultative care[64]. Currently, the emphasis is being placed on the primary level of healthcare management for diabetic patients by general practitioners across the world. The focus of diabetes care in SA is mainly on increasing patient knowledge through various means, placing a significant emphasis on health education. Most national initiatives and programmes in relation to diabetes are being led by the MoH, represented by the National Committee for Diabetes[32]. The committee works to carry out the MoH's plan of managing diabetes at the national level through different targeted programmes [65]. Those programmes are undertaken to fulfil the diabetes national plan's goals through several activities, including encouraging screening to avoid key risk factors, increasing the quality of diabetes care, encouraging diabetes-related research to improve patients' self-management, and engaging stakeholders in diabetes services development [65].

Proactive action in managing diabetes in a community setting is the most common approach in many developed healthcare systems worldwide where diabetes is being managed at the primary care level. Taking early action by treating people with diabetes in primary care and improving glycemic control before complications develop could lead to better health, social, and economic outcomes. On the contrary, the Saudi healthcare system is still taking reactive action to address the problem of T2DM at late stages rather than addressing it early [65]. Consequently, the Saudi population with diabetes often requires treatment for complications at secondary or

tertiary care levels [66]. This is further complicated by the fact that many individuals, both pre-diabetic and diabetic, often discover their condition at advanced stages due to a lack of awareness about the importance of early screening and diagnosis. This could be a reason for the number of patients receiving specialist care and receiving care as their conditions become more complex and require advanced care. The current healthcare provision for the accelerating number of patients is ineffective for the long term [65].

The standard diabetes care provided to the Saudi population, which is health education-based, is ineffective for long-term outcomes [67]. Although awareness-raising diabetes programmes are widely spread around the country, the knowledge related to managing T2DM is still suboptimal. A recent systematic review (2018) demonstrated that the Saudi population has inadequate knowledge regarding diabetes management [41]. Improvements in diabetes education-based programmes have not always resulted in the desired change. Research has shown that raising awareness is insufficient to promote better self-management practices [68].

2.3.2 Recent Changes to diabetes management in SA

Efforts have been made in SA to improve diabetes care for individuals with T2DM through the implementation of diabetes self-management programmes. However, the adoption and impact of these programmes remain limited, and T2DM continues to be a significant public health concern in the country [65]. Most current programmes rely on education as the core element to improve patients' self-care. However, the effectiveness of previous diabetes education programmes has fallen short of desired outcomes, as highlighted by past research [65]. From a psychological and theoretical viewpoint, educational-based interventions may fall short because they may fail to address other crucial factors [34]. These include individual motivation and behaviour change strategies. A systematic review of self-management studies for type 2 diabetes in Gulf Cooperation Council countries between 1996 and 2015 found that none of the

studies provided patients with the skills they needed to improve their ability to manage their condition, such as problem-solving skills [69]. This is consistent with theories like the Self-Determination Theory and the Social Cognitive Theory, which emphasise the importance of intrinsic motivation, self-efficacy, and problem-solving skills in successful self-management. Furthermore, none of the studies employed a patient-centred approach that prioritizes the patient as a collaborator rather than an educator, despite the evidence demonstrating that client-centred interventions tailored to the patient's needs are more likely to produce positive outcomes. [70].

2.3.3 Lifestyle intervention as a priority to address the T2DM

Arloski (2014) states, "Over half of what affects your health is your choice of lifestyle[71]." Lifestyle can be defined as individuals' health behaviours present in their daily lives[72]. For example, lifestyle behaviours encompass actions such as smoking, physical activity, diet, etc. Such behaviours normally ensue daily and engaging in these behaviours over a prolonged period can affect individuals' lives positively or negatively, depending on the nature of the behaviour.

Many epidemiological studies have proposed various variables to explain the significantly high level of T2DM: for example, obesity, dietary patterns, low medication adherence, and decreased levels of physical activity. It is widely acknowledged that lifestyle changes are crucial in supporting individuals with T2DM to adopt healthy behaviours that help manage their condition effectively. Personalised self-management approaches are highly encouraged for non-communicable diseases like T2DM[73 74]. Studies have shown that lifestyle modification programmes can greatly benefit high-risk individuals, resulting in a significant 58% reduction in the occurrence of T2DM[75 76]. The implementation of lifestyle intervention aims to mitigate the likelihood of chronic diseases and manage existing conditions. Adopting a healthy diet and

engaging in physical activities can reduce the risk of T2DM by 45%, irrespective of family genetics [53].

Inexpensive, effective, tolerable, and sustainable prevention efforts are imperative for limiting the T2DM epidemic. A US Diabetes Prevention Programme (DPP) clinical trial revealed that well-thought-out lifestyle interventions, such as providing training for pre-diabetics to encourage modest weight loss with the help of diet and physical activity reduced three-year diabetes occurrence by 58 % [77]. The DPP also carried out a 27-centre, randomised clinical trial to compare lifestyle interventions and pharmacological therapy (metformin) in terms of averting or deferring the occurrence of diabetes in people with diminished impaired glucose tolerance (IGT). The results revealed that lifestyle intervention and pharmacological therapy (metformin) were able to decrease the occurrence of T2DM[77]. Nevertheless, lifestyle interventions were observed to be more effective than metformin. The lifestyle interventions contributed to reducing the occurrence of T2DM by 58% compared to 31% in the metformin-treated group [77]. For long-term effectiveness, the significance of self-management skills has been stressed by several international diabetes organisations in enabling T2DM patients to address their individual management needs for better control of diabetes in the long run [60].

2.3.4 Need for Adopting a healthy lifestyle

With the alarming increase in the rate of T2DM in SA, patients must adopt a healthy lifestyle -being more physically active and consuming a healthy diet-for better management of their diabetes [78]. However, it appears challenging for people to stay motivated to adopt a healthy lifestyle, especially in the long term [79]. T2DM patients are often asked by their healthcare provider to follow certain lifestyles, behaviours and advices, such as adhering to medication, adopting a healthy diet, and being physically active to avoid diabetes complications and control their blood sugar. For many patients, these requirements are difficult to be accomplished and

maintained, especially in the long term. In addition, modifying behaviours requires patients to have different skills that enable them to improve and sustain a new healthy lifestyle. Many diabetes programmes in SA do not focus on improving patients' skills through their content[65]. Instead, the current programmes attempt only to address the T2DM issue by providing education/knowledge [80].

The MoH has recognised and emphasized the importance of shifting the current diabetes programmes' concentration from only providing related knowledge to changing behaviours [78]. It is crucial to understand why many individuals in SA with T2DM struggle to adopt healthy lifestyles despite many undertaken awareness-raising programmes. This step is significant, especially to effectively intervene by applying new tailored behaviour change programmes to support Saudi people with T2DM. Identifying and addressing potential barriers prior to an intervention implementation is crucial to optimize the desired effectiveness [81]. For better outcomes, behavioural change interventions should be grounded in evidence-based theories and frameworks [82].

2.4 Behaviour Change Wheel as a diagnostic tool for behaviour change interventions

An accurate diagnosis for the targeted problem, including potential barriers and facilitators, is vital for creating a systematic roadmap that starts with determining the real issue and ends with specifying target behaviours to achieve desired outcomes [83]. The Behaviour Change Wheel (BCW) was designed to assist in transitioning from behavioural diagnosis to the intervention development phase [82]. The COM-B model is the central element of the BCW, as shown in Figure 2.1, highlights the interactive factors of Capability, Opportunity, and Motivation, which are essential for effecting the desired behaviour in an intervention [83]. Furthermore, the TDF serves as a useful tool, offering extensive insights that connect the COM-B model and enhance comprehension of the required adjustments to tackle the targeted behaviour [84].

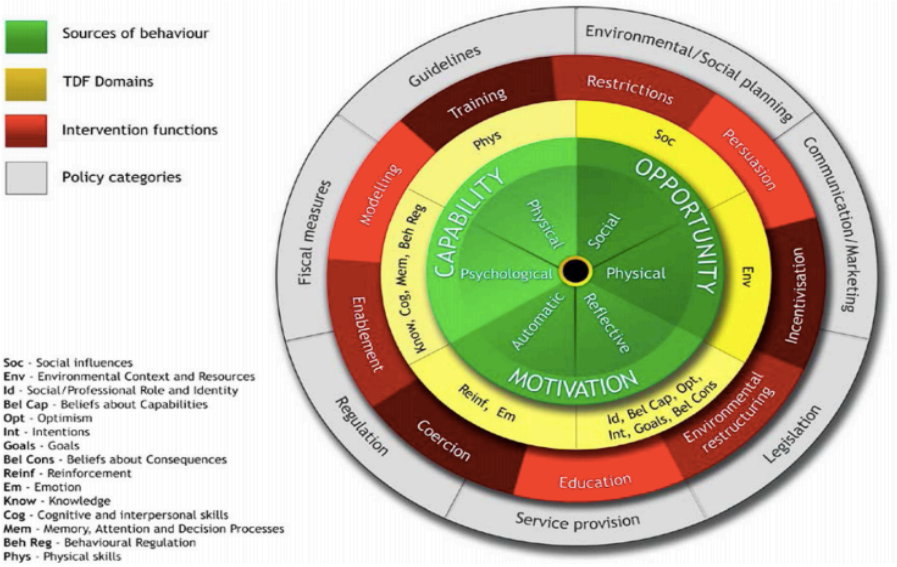

Figure 2-2: Behaviour Change Wheel Framework [1]

(Reproduced with permission from Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. Implementation Science 2011;6(1):42.)

2.4.1 Barriers to Adopting a healthy lifestyle for Saudi Patients with T2DM

Understanding the challenges that Saudi patients with T2DM face when trying to adopt a healthy lifestyle is important for tailoring health coaching interventions to their needs. A literature search was conducted to identify all existing papers that describe barriers to adopting a healthy lifestyle among people with type 2 diabetes in SA. Medline (Ovid) and Web of Science databases were used for this search. The search terms included 'type 2 diabetes,' 'barriers,' 'healthy lifestyle,' 'adaptation,' and 'Saudi Arabia.' The inclusion criteria required that studies be peer-reviewed and focus specifically on the context of Saudi Arabia. The initial search yielded 74 articles. Upon further examination, many articles were excluded due to

reasons such as not focusing on the Saudi context, not being directly relevant to the topic, or not being peer-reviewed. Eventually, six articles which met the criteria of describing barriers to lifestyle change in this population were selected for detailed review.

Studies were entirely reviewed, including qualitative research papers[65 80 85], systematic review[16], cross-sectional study[86], and narrative review[87], to identify the barriers faced by Saudi patients in managing T2DM by adopting a healthy lifestyle such as a healthy diet and physical activity. Alharbi (2018) conducted interviews with 33 healthcare providers in Riyadh, SA, aiming to identify barriers to patients' self-management of T2DM[85]. Similarly, Al Slamah (2020) interviewed 12 male and female patients with T2DM in Buriaydah, SA, to understand the obstacles hindering their self-management[80]. Alabdulbaqi (2019) involved conducting focus groups with 39 male and female healthcare providers in Dammam, SA, to evaluate the cultural adaptation of a diabetes self-management program for T2DM patients in primary healthcare centres [65]. Al-Hazzaa (2018) conducted a systematic review of 65 studies to identify barriers to physical inactivity in SA[16], while AlQuaiz A & Tayel S (2009) conducted a cross-sectional study involving 450 participants attending primary healthcare clinics in Riyadh to explore barriers to physical activity and healthy eating [86]. Additionally, Alneami Y & Coleman C (2016) conducted a literature review examining barriers to controlling T2DM in SA[87].

To systematically interpret the identified barriers, the COM-B model and TDF framework can be used to link the barriers to specific domains within the model and framework. These domains include the environmental context and resources, social influence, knowledge, physical skills, beliefs about capabilities, and beliefs about consequences. By categorizing these barriers based on their linkage to the COM-B model and TDF domains, the target behaviours necessary for desired changes can be identified[1]. Below is the analysis of barriers to the uptake of diet and physical activity using the COM-B model and TDF [88].

2.4.1.1 Environmental Context and Resources (OPPORTUNITY- PHYSICAL)

Various studies have posited that the organizational and environmental context structure plays a vital role as barriers to adopting a healthy lifestyle for T2DM in SA [16 80 86 87 89]. Across these studies, it has been clear that T2DM patients and health professionals were frustrated about the diabetes care system, including the long period for patients' follow-ups and the shortage in the healthcare capacity to accommodate the accelerating demand for diabetes services [80]. For example, health staff were still struggling to give enough time to hear diabetic patients' needs or educate them due to the high number of daily appointments. Therefore, many patients were left alone to figure out appropriate ways to manage their conditions. Multiple studies have shown that the longer the period patients spend with healthcare providers, the better patient outcomes and disease prevention become.

"Instead of checking 20 patients, we'd be better to see 15 or 13 patients only so that we have enough time to sit with the patient and hear about his needs and concerns if he needed to enquire about anything… this way, he would take the right time if the booking was not too much"[80].

By being forced to fit several agenda items into a visit of approximately 15 minutes, primary care clinicians are unable to fulfil the needs of every patient with a chronic condition [17]. Further, it is evident that around 50% of such patients do not understand what their doctor has advised them to do regarding their health during their primary care visits [90].

The Saudi healthcare system is ineffectively designed to provide the necessary support for diabetics at primary healthcare centres around the country. Numerous issues are raised by patients in relation to their need to travel outside their cities to get appropriate diabetes care [80].

Given that most primary care staff are not qualified to provide diabetes care, many patients have to visit secondary and tertiary care centres.

The lack of a safe and healthy environment due to the cities' design and extreme weather is another barrier that prevents people with diabetes from doing outdoor exercises [16 80 86 87]. In SA, an unsafe environment contributes to discouraging individuals from being physically active. For example, most students, especially in big crowded cities, tend to travel by car to go to their schools instead of walking or cycling [16]. Reliance on cars for transportation has become very common and is considered a restriction for daily physical activity [80].

"Cities are not designed to motivate physical activities in SA… women suffer more due to social restrictions that place them in indoor places" [85].

The climate in SA, characterized by prolonged periods of hot weather that can last for up to six months, acts as a deterrent for individuals wishing to engage in outdoor exercises [16 86 87]. Given that, a large part of Saudi Arabia is desert terrain, the overall weather conditions often discourage residents from maintaining a consistent exercise routine. Additionally, a lack of infrastructure, such as safe walkways, parks, and fitness facilities, adds to the challenge of staying physically active. The absence of safe cycling infrastructure in urban areas has caused a decrease in the number of people who enjoy cycling [16 87].

The dietary habits of the Saudi population have been greatly influenced by an unhealthy environment. Changes in the availability and distribution of various food restaurants in neighbourhoods have led to significant variations in people's diets. [87]. People with limited access to fast-food restaurants and greater accessibility to fresh market stores tend to have healthier dietary habits and a reduced risk of T2DM [91]. The prevalence of an unhealthy food

environment is especially noticeable among younger individuals, driven by the ubiquity of fast-food restaurants and limited access to healthier food alternatives [16 86].

2.4.1.2 Social influence (OPPORTUNITY-SOCIAL)

Individuals with T2DM face challenges in adopting healthier lifestyles due to societal influences and interpersonal relationships within Saudi culture [92]. In SA, the society is centred around a sense of community and characterised by shared values, norms, and traditions. These factors have a significant impact on individual behaviours and must be considered when promoting healthier lifestyles. A common practice within Saudi culture is for families and groups to gather for meals prepared at home. However, these meals may not meet the dietary needs of individuals with conditions such as diabetes or hypertension. As a result, these individuals may struggle to adhere to their diet plans, which can ultimately hinder their ability to control their dietary intake. In addition, family members tend to seek advice, support and rely on each other. In some situations, reliance on others may negatively affect behaviour leading to undesirable results, especially in preventive care.

"I have often seen parents who consider being overweight as a sign of good health. They do not see it as a sign of poor lifestyle. Actually, they see lean kids as possessing poor health, even if the kid is lean because of an active lifestyle"[85].

Saudi patients with T2DM have highlighted the substantial influence of societal norms and attitudes, which pose a considerable hindrance to disease management [16 80 86 89]. The culture of extended families often involves frequent daily (2-3 times) and monthly gatherings, which, unfortunately, undermine adherence to a healthy lifestyle for individuals with T2DM. The food consumed at these gatherings typically has high levels of carbohydrates, fats, and sugars [92].

Hospitality is deeply ingrained in Saudi culture and often manifests in the form of food offerings to guests. It's considered impolite for guests to refuse a meal invitation, which typically involves a diet high in fat, carbohydrate, and sugar content. The cultural norm of urging guests to eat generously, viewed as a sign of respected hospitality, complicates T2DM patients' efforts to adhere to a healthy diet. Considering the complexity of these socio-cultural factors associated with dietary habits is crucial when attempting to influence the lifestyle behaviours of Saudi individuals. A recent study indicated that 72.4% of the participants identified the lack of social support as a barrier to adhering to a healthy diet [86]. In fact, studies consistently cite cultural and social pressure as significant obstacles that people with diabetes encounter, hindering their commitment to a healthier lifestyle.

"We need more support. I can tell you that the Saudi people have many events and occasions which contain eating food. The life became hard. i.e. referring to the pressure of social (eating), and the negative view for not joining in"[80].

The social impact extends beyond adopting a healthy diet and also affects individuals' physical activity. A significant barrier to physical activity in SA is the lack of social support, which affects approximately 77% of individuals[86] It is widely acknowledged that behaviour change programmes are more successful when close relatives are involved in the interventions[10]. In the past, it was socially inappropriate to walk or run inside neighbourhoods, leading people to rely on cars to travel to less populated areas of the cities for exercise. Although physical activity is becoming more widely acknowledged as important, especially among younger, more educated individuals, a significant portion of the population continues to live a sedentary lifestyle[9].

2.4.1.3 Knowledge (CAPABILITY-PSYCHOLOGICAL)

The lack of knowledge has been frequently reported across several studies as a hindrance that negatively impacts people with T2DM to adopt a healthy lifestyle [16 41 80 86 87 93]. It is evident that the lack of knowledge about diabetes leads Saudis with T2DM to hold misconceptions [87]. A recent study by Al-Khudairy et al. (2014) found that 83% of people with T2DM thought having snacks helped in controlling blood sugar, whereas 66% believed consumption of bitter food would balance their hyperglycemia [92]. Misconceptions related to diabetes arise from relying on unreliable sources of knowledge, including social media applications (Apps) [94].

"People here disseminate wrong information on WhatsApp, such as (I did this, and my diabetes went away!) and they propagate this message in multiple groups. And when you explain to them that this is totally wrong information you can easily see the shock in their face"[85].

"We find that many Saudis, as a religious community, are extremely trusting of the views and practices of the traditional healers" [85].

"Many patients often come up to my clinic with misconceptions about diabetes. When I asked them about the source of their information, the answer is usually (it's Known), (my relatives) or (my friends)" [85].

"Most people do not know about diabetes symptoms. So they do not know that the problems they are facing have resulted from diabetes" [85].

"Patients often come to us with problems which can be directly related to diabetes. When we ask them for blood tests, they ignore us. They think blurred vision and tiredness are natural in middle and older ages and link it to stress, but not to diabetes. There is a serious lack of awareness of diabetes. Many individuals seek alternative care from traditional healers for symptoms which are actually caused by diabetes" [85].

Interestingly, healthcare professionals also lack knowledge about the skills needed to enable patients to manage their disease, as there is no formal application of systematic self-management programmes in SA [80].

"I personally know nothing about them. [i.e. in his reply to if systematic self-management programmes have previously been applied]"[80].

"We need a local framework and guidelines to guide the delivery of care in SA" [80]

"They will be a good addition if we had standardised guidelines adopted by all medical team" [85].

The poor knowledge related to diabetes leads to the proliferation of misconceptions, including the widespread use of herbs and alternative medicine. Various studies conducted in three cities

in SA have concluded that about a third of individuals with T2DM use herbs and alternative medicine due to poor knowledge [95-97]. A qualitative study conducted by Alharbi (2018) demonstrated physicians' encounters with patients with distorted knowledge about T2DM patients[85].

"Patients believe that traditional medicines will not cause any harm, if not any good. The problem is that they delay their treatment, and this causes a lot of problems. They have to be taught that traditional medicines are not proven to treat diabetes" [85].

"I've heard of at least 30 to 40 different traditional treatments of diabetes from my patients: people tell you about moringa, garlic, and unknown herbs. Some people believe that it is some sort of envy or magic, so we just need to go to traditional healers or an Imam to perform an exorcism" [85].

Saudi society has long been known for its conservatism. Islam has a significant influence on Saudi culture as it is the birthplace of Islam. The impact of religion and culture goes beyond behaviours and attitudes and also shapes individuals' perceptions of their lives [98]. Insufficient Islamic knowledge and misconceptions about diabetes often lead to confusion among patients, resulting in misguided beliefs and attitudes towards diabetes management. Based on religious misconceptions, some Saudis with T2DM believe that consuming food with a high glycaemic index, including consuming a lot of honey and dates, can help control diabetes without affecting blood sugar levels. Additionally, some individuals strictly adhere to religious texts while misunderstanding their intended meaning [85]. As a result, some individuals with diabetes who struggle to manage their condition become frustrated and accept their fate. Fatalistic patients believe that nothing can be done about their predetermined destiny. The distorted

views of health held by these patients can be attributed to their lack of knowledge, leading them to give up and rely on Allah to manage their condition[65].

2.4.1.4 Physical skills (CAPABILITY-PHYSICAL)

Patients in various studies have consistently identified a lack of physical skills and energy as a significant barrier to engaging in physical activity [16 86 89 93]. Specifically, older and obese individuals with T2DM have highlighted the issue of experiencing pain during exercise, which hinders their ability to stay physically active [89].

2.4.1.5 Beliefs about capabilities (MOTIVATION-REFECTIVE)

Recent studies have reported that a lack of willpower and self-confidence in one's abilities is directly linked to difficulties in maintaining a healthy lifestyle [16 80 86]. Lack of willpower is the most common barrier that hinders people with T2DM from staying motivated and following a healthy diet. In a study group, patients who lacked willpower accounted for 80.3% (354 out of 441) [86]. People with T2DM have expressed their unwillingness to engage in physical activity without any specific reason [80].

"When I suffered from diabetes, the doctors advised me to walk. I didn't used to walk at all, and I didn't try. So, my mistake is that I didn't try to walk" [80].

Financial incapability is a significant barrier that hinders individuals with T2DM from maintaining a healthy lifestyle. While healthcare is free in SA, additional costs such as diabetes monitoring devices and purchasing healthy food pose challenges. Additionally, many patients

cannot afford the expenses associated with physical activity facilities or joining fitness centres [80].

"I have a comment on the doctor's talk about the support matter. There are many patients who suffer from the cost; the ministry did not provide everything till now, so when I ask the patient to undergo an analysis he says: it costs too much and I can't afford it Moreover, most of them do not have a Diabetes Analysis Device, they can't afford buying it, hence, it will affect them as well" [80].

"But some patients are unable to go to the health club, for examples they do not have subscription [reduced fee membership] or the financial ability to go there, to be honest, most patients" [80].

2.4.1.6 Beliefs about consequences (MOTIVATION-REFLECTIVE)

Some individuals with T2DM have concerns about the consequences of physical activity. Fear of injury acts as a barrier that discourages certain patients, especially older and obese individuals, from exercising [86 89]. This fear becomes more apparent if a patient has a history of previous injury or is prone to further injury.

2.4.2 Identification of intervention behaviour targets

In SA, there are currently no official guidelines for managing type 2 diabetes through healthy lifestyle choices. Therefore, we have referred to the UK's guidelines on lifestyle as they share similarities in their healthcare systems [69 99]. These guidelines have been used to determine the most suitable behaviour targets for the Saudi context. We consulted healthcare professionals

in the intervention setting, including a dietician, to establish these targets. Through collaborative discussions, we assessed and prioritized behaviours based on their potential impact, the feasibility of measurement, and achievability. As a result of this process, we have proposed four behaviour targets [1].

The four proposed behaviour targets are as follows [100]:

- Decrease carbohydrate intake for each meal
- Use unsaturated fats where possible (avoid saturated fats)
- Do exercise for 30 min, five days on a weekly basis
- Monitor waist circumference and maintain it below (80 cm for women and 94 cm for men)

Table 2.1 demonstrates the influences upon each selected behaviour to bring about the intended change through a participant's capability, opportunity, and motivation. The table presents the details based on the information identified from previous literature.

2.4.3 Identification of intervention functions and behaviour change techniques (BCTs)

To determine the most suitable intervention functions and potential BCTs, we employed the COM-B model and TDF while drawing on relevant research from literature reviews. The selection process was guided by the APEASE criteria (see Appendix 1), which assess the appropriateness of the chosen functions and techniques based on affordability, practicality, effectiveness and cost-effectiveness, acceptability, side-effects/safety, and equity[101]. This approach aligns with the guidance provided by the BCW. For more detailed information on the selected intervention functions and BCTs (see Chapter 4).

COM-B		TDF coding included in this research	What needs to occur to bring about change?			
			Decrease carbohydrate intake in each meal	Use unsaturated fats as possible (avoid saturated fats)	Do exercise for 30 min, five days on a weekly basis	Monitor waist circumference
Capability	Psychological	Knowledge	Knowledge: Understand food types (especially carbohydrate types, e.g., rice and dates) Understand carbohydrate quantity targets Understand alternative food (contain many fibres) to replace carbohydrate to avoid hunger	Knowledge: Understand food types in terms of fats included Understand unsaturated fats sources Start learning how to cook to take control of meals' components	Knowledge: Understand the role of PA and its impacts in simple language Understand how to do exercise (indoor and outdoor) Understand what the most suitable and enjoyable exercise	Knowledge: Understand the associations between waist circumference and T2DM Understand the recommended target for waist size Understand how to maintain a good size
	Physical	Physical skills	How to measure carbohydrate quantity	NA	Have the energy and the required skills to do PA	Taking the measurement frequently for comparison
Opportunity	Social	Social influences	Having social support, e.g., family members or friends to stay motivated to change the behaviour Preparing your own meal as possible when you outside the house Explain and kindly refuse any meal would hurt your diet (many dates, rice, sweets…etc.)	Having social support, e.g., family members or friends, to stay motivated to change the behaviour Preparing your own meal as possible when you outside the house Explain and kindly refuse any meal that would hurt your diet e.g., unsaturated fats	Having social support, e.g., family members or friends, to stay motivated to change the behaviour Meeting people at parks to walk together	Having social support, e.g., family members or friends, to stay motivated to change the behaviour
	Physical	Environmental context and resources	Avoid eating fast food as possible Buy food that contains many fibres	Avoid eating fast food as possible Buy food that contains unsaturated fats	Register in a fitness centre, if possible, to avoid any environmental restrictions Buy essential PA equipment, if possible, to avoid any environmental restrictions Have daily time for PA Do the most suitable and enjoyable exercise	Have a tape to measure waist circumference

COM-B		TDF coding included in this research	What needs to occur to bring about change?			
			Decrease carbohydrate intake in each meal	Use unsaturated fats as possible (avoid saturated fats)	Do exercise for 30 min, five days on a weekly basis	Monitor waist circumference
Motivation	Reflective	Beliefs about own capability Beliefs consequences Social role and identity	Beliefs about own capability: Have willpower and self-confidence in the ability to make the change Have alternatives to cope with financial incapability Beliefs about consequences: Understand the negative impacts of much carbohydrate intake Understand the risk factors for developing other diseases Social Role and Identity: Address the social barrier (carbohydrate portion size, like using a spoon)	Beliefs about own capability: Have willpower and self-confidence in the ability to make the change Have alternatives to cope with financial incapability Beliefs about consequences: Understand the negative impacts of food containing saturated fats Understand the risk factors of having saturated fats in developing other diseases Social Role and Identity: Address the social barrier (using unsaturated fats for cooking)	Beliefs about own capability: Have willpower and self-confidence in the ability to do the exercise Beliefs about consequences: Overcome the fears of injury Understand the risk factors of being physically inactive Social Role and Identity: Address the social barrier (overcome social barriers related to PA)	Change self-view of waist circumferences Beliefs about consequences: Understand the significance of accomplishing the waist circumference target

Table 2-1: Description of the selected TDF domains to identify what needs to be changed

SECTION 2.5: Health Coaching

2.5.1 Definitions and Theoretical Basis

Health coaching, as defined by the International Coach Federation (ICF), involves working with clients as an ally to stimulate their thinking in a creative way that empowers them to fully utilise their personal and professional potential [102]. Zeus and Skiffington (2000) define it as "*Coaching is about learning – yet a coach is not a teacher and does not necessarily know how to do things better than the coachee. A coach can observe patterns, set the stage for new actions, and then work with the individual to put these new, more successful actions into place. Coaching involves learning. Through various coaching techniques such as listening, reflecting, asking questions, and providing information, coachees become self-correcting (they learn how to correct their behaviour themselves) and self-generating (they generate their own questions and answers)*"[103].

Health coaching, according to Wolever et al. (2013), is "a patient-centred approach wherein patients at least partially determine their goals, use self-discovery or active learning processes together with content education to work toward their goals, and self-monitor behaviours to increase accountability, all within the context of an interpersonal relationship with a coach"[21]. Health promotion interventions are often grounded in different theories, including psychological theories, to effectively predict and understand how a particular behaviour is being modified.

The ICF has identified eight coaching competencies to support a greater understanding of the importance of health coaching skills that coaches should use (see Table 2.2). The competencies are classified into four groups that fit logically with each other to help the health coach conduct effective intervention sessions.

Table 2-2: ICF Core Coaching Competencies [102]

Core Competencies	How it Connects
A. Foundation	**1. Demonstrates Ethical Practice:** Definition: Understands and consistently applies coaching ethics and standards of coaching **2. Embodies a Coaching Mindset:** Definition: Develops and maintains a mindset that is open, curious, flexible, and client-centred.
B. Co-Creating the Relationship	**3. Establishes and Maintains Agreements:** Definition: Partners together with the client and relevant stakeholders to create clear agreements about the coaching relationship, process, plans, and goals. Establishes agreements for the overall coaching engagement as well as those for each coaching session. **4. Cultivates Trust and Safety:** Definition: Partners together with the client to create a safe, supportive environment that allows the client to share freely. Maintains a relationship of mutual respect and trust. **5. Maintains Presence:** Definition: Is fully conscious and present with the client, employing a style that is open, flexible, grounded, and confident
C. Communicating Effectively	**6. Listens Actively:** Definition: Focuses on what the client is and is not saying to fully understand what is being communicated in the context of the client systems and to support client self-expression **7. Evokes Awareness:** Definition: Facilitates client insight and learning by using tools and techniques such as powerful questioning, silence, metaphor or analogy
D. Cultivating Learning and Growth	**8. Facilitates Client Growth** Definition: Partners with the client to transform learning and insight into action. Promotes client autonomy in the coaching process.

2.5.1.1 Health belief model (HBM)

The *Health Belief Model* (HBM) was developed in the 1950s to understand the reasons people fail to uptake preventive health actions and activities. It is a widely used theory in the field of

health behaviour change [104]. The HBM posits that six constructs predict health behaviour: (i) risk susceptibility, (ii) risk severity, (iii) benefits to action, (iv) barriers to action, (v) self-efficacy and (vi) cues to action [105].

2.5.1.2 Transtheoretical Model (stages of change)

Transtheoretical model (TTM) is one of the most commonly used theories in behavioural change interventions [106]. TTM suggests that changes occur through five stages: (i) pre-contemplation, (ii) contemplation, (iii) planning, (iv) acting and (v) maintaining (Prochaska [107] [108]. The TTM was developed to understand the mechanisms of behaviour change and categorizes the processes of change into stages to explain how desired behaviours are achieved [107] [108].

2.5.1.3 Self-determination Theory

Self-determination theory is a "theory of motivation and self-regulation that proposes personally-relevant goals are more internally motivated (versus externally motivated goals) and are thus more likely to be achieved than goals set due to some external pressure" [109]. It proposes that goals that align with individuals' autonomy, competence, and relatedness are more likely to be achieved [109]. This theory provides a foundation for understanding motivation and development, with internal motivation being facilitated by these factors to integrating behaviours into daily life [110].

2.5.1.4 Motivational Interviewing

Motivational interviewing (MI) is a one-on-one counselling approach that works in conjunction with the stages of change to help individuals explore their ambivalence toward change and increase their motivation to change [111]. The main goal of MI is to address clients' ambivalence by allowing them to make their case for change and reducing resistance talk [112]. MI aligns with

self-determination theory by creating conditions that foster behavioural change and promote client autonomy and responsibility [113] [114].

MI is intensely focused on constructing clients' autonomy to allow them to feel self-regulation and responsibility [109]. It is crucial since patients are often asked to do certain things and are not given the freedom to choose. On the contrary, in the health coaching session, a client is responsible for designing and initiating self-monitoring of his/her health status. This skill allows patients to practice their personal autonomy to determine whether or not they can outweigh the advantages and disadvantages and empowers them with the accountability to do so.

2.5.1.5 Cognitive Behaviour Therapy (CBT)

CBT is a therapeutic method premised on the idea that detrimental behaviours are learned responses reinforced by negative and frequently irrational thought patterns, resulting in adverse emotions. These behaviour and emotional patterns can impede positive change. CBT helps clients in cultivating more optimistic and logical thinking about themselves, which can alter their emotional responses and bolster their self-efficacy[115]. It involves challenging negative and unhelpful thoughts and transforming them into opportunities for change.

2.5.2 Health coaching growing in popularity

Health coaching has increasingly been acknowledged as an effective intervention for conditions associated with lifestyle choices, such as T2DM [116]. The rising focus on self-care and preventive models within healthcare systems has played a significant role in endorsing the value of health coaching [18]. Since wellness is a relatively individual issue, there is increasing evidence supporting the fact that people need an ally -client-centred- to work with [71]. Health coaching is derived from different disciplines, including health education and counselling. These fields provide an educational focus to healthcare interventions, a method that gained

popularity in the 1950s. Specifically, this approach provides patients with education in the form of information and advice to effect behaviour changes and reduce health risks to improve overall health status [117].

Positive psychology is the central pillar of health coaching that focuses more on clients' present and future and what can work for them by harnessing their strengths to make positive changes [118]. This is also supported by Butterworth et al. (2007), who stated that health coaching represents a holistic approach that focuses on positive lifestyles and behaviour changes to enhance health by providing the necessary resources for behaviour change[117]. Physical therapists and physicians can assist in the success of behaviour-change approaches by employing health coaching practices to incorporate more client-centred care relationships [18].

Health coaching empowers individuals to effectively engage in improving their skills by assuming the role of decision-making. Specifically, they are encouraged to understand and actively participate in self-monitoring their health conditions, striving to achieve planned short- and long-term health goals. The health coaching approach considers individuals' priorities in relation to their health, taking into account their beliefs and values. It grants individuals the freedom to choose healthier food options and engage in regular physical activity, allowing them to modify their lifestyle and work towards realizing their goals, such as reducing A1c levels, without solely relying on medication as the initial solution. [119].

2.5.3 Health coaching as a promising approach to T2DM management in SA

Health coaching is a potential strategy that might be beneficial for managing T2DM in SA. The MoH in SA is actively working towards a patient-centred healthcare model and improving healthcare delivery to reduce hospitalization rates and achieve the goals of the Healthy Society 2030 initiative [27]. T2DM has been prioritized as a key disease for measuring the success of these efforts. Health coaching, while still under evaluation, seems align with these goals and may contribute to the overall vision of a healthy society [27].

Health coaches could potentially offer support that might help reduce the time pressure on health practitioners[68]. While health coaching seems promising, more comprehensive research is required to validate its effectiveness in addressing the existing gaps in diabetes care in SA. Health coaching reinforces health education provided during patients' clinic time and may offer an opportunity for patients to better understand their disease management. It integrates the necessary skills for individuals to take an active role in self-management [120].

Some studies suggest that health coaching that is in line with patients' values might have certain advantages over traditional T2DM education programmes [121]. This approach has the potential to be cost-effective and could help enhance patients' self-confidence and skills, such as goal-setting and problem-solving [122]. Moreover, it might help ease the burden on healthcare providers and potentially reduce the expenses related to caring for and treating people with T2DM in SA. While coaching programmes emphasizing nutrition and exercise have shown some promise in managing chronic conditions like T2DM4 [4 23], more rigorous evaluations are needed. Overall, while health coaching holds promise for the management of T2DM in SA, more research is needed to ascertain

its effectiveness in achieving better patient outcomes and supporting the country's healthcare objectives [123].

2.5.4 Health coaching content

The use of theories is essential, as advocated by the Medical Research Council (MRC) guidelines, in health coaching to optimize intervention efficiency, and ensure a logical understanding of the complex factors involved before the actual implementation [124] [125].

Health coaching for people with T2DM is a complex intervention that involves many different factors that impact its effectiveness. Drawing from multiple behaviour change theories, health coaching for individuals with T2DM requires careful consideration and evaluation to achieve successful replication. However, the selection of theories in previous health coaching studies has lacked clear criteria and scientific-based choices, leading to variations in outcomes and effectiveness[4]. Given this, the selection of theory is likely based on a personal view rather than a scientific-based choice [126]. To address this, it is crucial to understand the internal structure of health coaching interventions, including session frequency, duration, content, intervention duration, and session delivery. These factors significantly impact the intervention's effectiveness[4].

The heterogeneity observed in health coaching interventions has made it challenging to identify the most effective methodological factors for future replication [4]. Inadequate description and unclear details of intervention content hinder the determination of active ingredients, resulting in the frequent use of ineffective techniques and a lack of understanding of effective replication mechanisms [88]. To overcome these challenges, health coaching programmes should be well-defined, rigorous, and guided by a comprehensive model or framework [127].

While health coaching has recently been introduced in Saudi healthcare systems for weight loss in primary care settings[22], its adaptation and implementation for specific conditions like T2DM remain unclear. Thus, a systematic review (see Chapter 3) was undertaken to examine health coaching content. The systematic review sought to explore the theoretical basis and the most effective active ingredients -Behaviour Change Techniques (BCTs)- of health coaching to inform the adaptation of the intervention curriculum (see Chapter 4 & Appendix 10) and provide valuable insights for the intervention's implementation.

SECTION 2.6: Aims and Objectives

2.6.1 Overall research aim

This research aims to explore the feasibility and acceptability of tailored health coaching in SA, which could aid those with T2DM in more effectively managing their conditions.

2.6.2 Research objectives:

1. To undertake a systematic review to explore the content of health coaching, active ingredients (BCTs), and theoretical bases in related literature (see Chapter 3) to inform the intervention implementation process (see Chapter 4)
2. Link the identified barriers (see Chapter 2) to intervention functions and behaviour change techniques in the systematic review (see Chapter 3) to inform a tailored feasibility health coaching intervention (see Chapter 4).
3. To undertake a mixed methods feasibility RCT to assess the feasibility and acceptability of the health coaching intervention to participants through patients' and health coaches' experience and to explore how the coaching programme could be improved/tailored for Saudi patients in a future full-scale trial (see Chapter 4) by:

- Assessing recruitment, and retention rates, and estimating the effect size;
- Assessing the implementation process, including data collection procedures;
- Assessing and determining the sample size for the larger-scale trial using the findings of this feasibility study;
- Exploring the acceptability and suitability of intervention through participants' perceptions of, and experiences with, the health coaching intervention.

CHAPTER 3: **Systematic Review and Meta-Analysis**

Behavioural Change Techniques in Health Coaching-Based Interventions for Type 2 Diabetes Patients: A Systematic Review and Meta-Analysis

3.1 Chapter overview

Health coaching, a promising new approach employed in various contexts, has been widely accepted for its role in facilitating behavioural changes[4]. While many studies have highlighted the effectiveness of health coaching in addressing diverse chronic conditions, including T2DM [23], other research findings suggest that the impact of health coaching on treating individuals with T2DM may be minimal or inconclusive[4]. Yet, there is a lack of consensus about how health coaching interventions should be carried out and what the most effective theories or behaviour change techniques (BCTs) should be used to guide such interventions [4]. Recent systemic reviews of RCT trials examining the use of health coaching have yielded varied outcomes, with some reporting its effectiveness and others asserting its ineffectiveness [4 23]. This is also supported by another systemic review by Radwan et al. (2019), which has indicated the issue of the lack of guidance, variation and mixed reported outcomes among the interventions' findings[128].

In light of the lack of consensus on designing an effective health coaching intervention and the absence of guidance on directing the development process, including the selection of a suitable theoretical basis, replicating similar interventions becomes challenging. This is particularly true in a new context, such as SA, without understanding the reasons behind the inconsistent results of the efficacy of health coaching. The pressing question that needs addressing is how to select and

implement a health coaching intervention effectively to maximise its potential and achieve optimal efficiency. This systematic review sought to bridge the current gap by investigating the content of health coaching programmes, exploring how the active ingredients (BCTs) have been used across those interventions, and discovering the significant components of their effectiveness for successful replication.

The present chapter attempts to address the first research objective by undertaking a systematic review to explore the content of health coaching; active ingredients (BCTs). This chapter has been peer-reviewed and published through an open-access journal, BMC public health, under the Creative Commons Attribution (CC-BY) license. As an open-access journal, we were allowed to reuse without any restrictions the final published PDF of the paper. The following pages maintain the layout of the final publication.

3.2 Authors' Contributions

This paper involved the collaboration of five co-authors: Hannah Hartley, Paul Norman, Samantha Caton, Onur Dogru, and Elizabeth Goyder. Abdullah Almulhim served as the first author and corresponding author and was responsible for conceptualizing the idea, synthesising and analysing data from various sources, writing and reviewing the main manuscript, and editing the article. Abdullah Almulhim was responsible for applying for research funding (publication fee). Both Abdullah Almulhim and Hannah Hartley worked together to code the intervention content, identifying specific Behaviour Change Techniques (BCTs). Paul Norman played a role as a mediator, assisting in reaching a consensus on the identified BCTs. Doğru OC contributed to conducting the meta-analysis, which was then reviewed by Paul Norman. Elizabeth Goyder and Samantha Caton provided critical feedback and reviewed the manuscript.

3.3 Publication reference

Almulhim AN, Hartley H, Norman P, Caton SJ, Doğru OC, Goyder E. Behavioural Change Techniques in Health Coaching-Based Interventions for Type 2 Diabetes: A Systematic Review and Meta-Analysis. BMC Public Health. 2023 Dec;23(1):1-21. https://doi.org/10.1186/s12889-022-14874-3

Almulhim *et al. BMC Public Health* (2023) 23:95
https://doi.org/10.1186/s12889-022-14874-3

BMC Public Health

RESEARCH Open Access

Behavioural Change Techniques in Health Coaching-Based Interventions for Type 2 Diabetes: A Systematic Review and Meta-Analysis

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Abstract

Background Given the high rates globally of Type 2 Diabetes Mellitus (T2DM), there is a clear need to target health behaviours through person-centred interventions. Health coaching is one strategy that has been widely recognised as a tool to foster positive behaviour change. However, it has been used inconsistently and has produced mixed results. This systematic review sought to explore the use of behaviour change techniques (BCTs) in health coaching interventions and identify which BCTs are linked with increased effectiveness in relation to HbA1C reductions.

Methods In line with the PICO framework, the review focused on people with T2DM, who received health coaching and were compared with a usual care or active control group on HbA1c levels. Studies were systematically identified through different databases including Medline, Web of science, and PsycINFO searches for relevant randomised controlled trials (RCTs) in papers published between January 1950 and April 2022. The Cochrane collaboration tool was used to evaluate the quality of the studies. Included papers were screened on the reported use of BCTs based on the BCT taxonomy. The effect sizes obtained in included interventions were assessed by using Cohen's d and meta-analysis was used to estimate sample-weighted average effect sizes (Hedges' g).

Results Twenty RCTs with a total sample size of 3222 were identified. Random effects meta-analysis estimated a small-sized statistically significant effect of health coaching interventions on HbA1c reduction ($g_+ = 0.29$, 95% CI: 0.18 to 0.40). A clinically significant HbA1c decrease of $\geq$5 mmol/mol was seen in eight studies. Twenty-three unique BCTs were identified in the reported interventions, with a mean of 4.5 (SD = 2.4) BCTs used in each study. Of these, *Goal setting (behaviour) and Problem solving* were the most frequently identified BCTs. The number of BCTs used was not related to intervention effectiveness. In addition, there was little evidence to link the use of specific BCTs to larger reductions in HbA1c across the studies included in the review; instead, the use of *Credible source* and *Social reward* in interventions were associated with smaller reductions in HbA1c.

Conclusion A relatively small number of BCTs have been used in RCTs of health coaching interventions for T2DM. Inadequate, imprecise descriptions of interventions and the lack of theory were the main limitations of the studies included in this review. Moreover, other possible BCTs directly related to the theoretical underpinnings of health

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coaching were absent. It is recommended that key BCTs are identified at an early stage of intervention development, although further research is needed to examine the most effective BCTs to use in health coaching interventions.

Trial registration https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42021228567.

Keywords Health behaviour change, Health coaching, Self-management, Behaviour change techniques, Type 2 diabetes

Background

Type 2 Diabetes Mellitus (T2DM) is a chronic condition that is a significant public health concern. It was estimated that 462 million of the global population had T2DM in 2017, with this figure projected to increase by 6.28% up to 491 million people globally by 2030 [1]. T2DM is associated with an increased risk of co-morbidity and other health implications, such as heart and stroke disorders, eye problems and complications with hearing, kidney failure, nerve injury, amputations, oral issues, and foot problems [2]. Having a raised body mass index (BMI), low physical activity levels and unhealthy dietary patterns are key contributing factors of developing T2DM [3]. Fortunately, these lifestyle behaviours are modifiable through intervention which can reduce the risk of developing the condition [4]. However, recent economic growth has generated an obesogenic environment, resulting in the widespread availability of affordable unhealthy foods and an increase in sedentary lifestyles. This perpetuates unhealthy dietary patterns and low physical activity levels, and presents challenges to attempts to modify lifestyle behaviours to reduce the risk of developing T2DM [5].

Supporting people with T2DM to self-manage their condition is considered key to successfully changing lifestyle behaviours to reduce the risk of T2DM associated health implications [3]. Successful self-management and behaviour change in people with T2DM can significantly reduce or delay chronic conditions associated with T2DM by at least 75% [6]. This has led many healthcare systems to adapt their care of T2DM to focus on self-management and individualised behaviour change, requiring a more client-centred approach [7]. Individualised, self-management approaches for non-communicable conditions such as T2DM are increasingly being advocated [8, 9]. Among those at high risk, randomized controlled trials have shown that altering one's lifestyle can reduce the risk of acquiring diabetes by 58% in people with impaired glucose tolerance [10, 11]. To date, self-management behaviour change T2DM interventions can be characterized mainly by their emphasis on the role of education and motivation as strategies for behaviour change. These interventions have resulted in only short term behaviour change, with poor effects in enabling targeted people to maintain the self-management skills needed to make long-term behaviour change [12–15].

Health coaching based interventions have been proposed as a more appropriate approach in achieving long term behaviour change for the self-management of T2DM [16]. Health coaching is a one-to-one support intervention style described by Wolever et al. as "a patient-centred approach wherein patients at least partially determine their goals, use self-discovery or active learning processes together with content education to work toward their goals, and self-monitor behaviours to increase accountability, all within the context of an interpersonal relationship with a coach" [17]. Health coaching grew out of counselling and health education fields [18], and has been widely used in different contexts as an intervention for addressing lifestyle-related conditions, including T2DM [16]. The growing acceptability of health coaching aligns with the shift towards a more person focussed self-management model in healthcare settings [6].

Many studies have shown the efficacy of using health coaching with different chronic conditions, including T2DM [19]. However, recent systemic reviews of randomised controlled trials utilising health coaching have reported mixed results, with some reporting that health coaching is effective, while others claim it is ineffective [19, 20]. One of the contributing factors of inconsistent findings across these studies is the lack of consensus on the active ingredients and content to be included in health coaching interventions [17]. In general, a lack of guidance, inappropriately selected intervention components and variation in the reporting of outcomes has been suggested to contribute to the mixed evidence for effectiveness of health coaching interventions [21–23]. Consequently, there is currently no consensus in the literature on designing an effective health coaching intervention, including the selection of a suitable theoretical basis and active components for behavior change [20]. In the absence of such consensus, there is uncertainty towards which coaching methods are more appropriate and effective to replicate and use; this includes the intervention content, duration, length, and mode of delivery of sessions [24].

To support the systematic application of active components to change behaviours, the behaviour change technique taxonomy (BCTTv1), can be applied. The BCTTv1 is an extensive taxonomy of behaviour change techniques (BCTs) that can be utilised as active behaviour change components in behaviour change interventions [25]. A BCT is defined as "an observable, replicable, and irreducible component of an intervention designed to alter or redirect causal processes that regulate behaviour" [25]. The taxonomy consists of 93 BCTs clustered into16 groups. BCTs can be used with numerous theoretical perspectives, in isolation or in combination with other BCTs. The development and evaluation of interventions incorporating BCTs may enable researchers to systematically apply, identify and report the key 'active ingredients' in interventions [25]. This, in turn, may generate understanding of effective active components in behavior change interventions targeting T2DM and increase the possibility of replication [25].

A number of reviews have highlighted that the use of BCTs in interventions that target behaviours related to physical activity and maintaining a healthy weight may result in better management of HbA1c in people with T2DM [26]. For example, employing certain BCTs in dietary interventions, such as *instruction on how to perform a behavior*, *demonstration of the behavior*, *behavioral practice/rehearsal*, and *action planning*, has linked to a greater impact on HbA1c levels for people with T2DM [27]. Similarly, the use of two BCTs, *goal setting* and *review of behavior/outcome goals,* has been shown to have a positive impact on reducing fat intake for people with T2DM [28]. Another review of web-based interventions found that using the BCTs of *feedback on behavior, information about health consequences*, *problem solving*, and *self-monitoring of behavior*, was linked to improvements in changing behavior, psychological conditions clinical parameters in people with T2DM [29]. The BCT of *social support, natural consequences, antecedents, associations, shaping knowledge, social support* and *goals* were used most frequently in interventions that target T2DM [30]. A recent review urged employing the following BCTs when developing psychological interventions that target T2DM to improve HbA1c; *social support (unspecified), problem solving*, and *goal setting (behavior)* [31]. The findings of these reviews indicate that a detailed analysis of the BCTs used in health coaching interventions for T2DM, and the extent to which they are associated with greater reductions in HbA1c, is likely to aid the development and replication of effective health coaching interventions for T2DM.

This review therefore aimed to bridge the current gaps in knowledge by addressing the four main objectives. It sought to: 1) Assess health coaching intervention content in relation to reporting sufficient and precise descriptions of used behaviour change theories and BCTs; 2) Identify the BCTs used in health coaching interventions; 3) Assess whether the inclusion of specific BCTs are associated with larger effect sizes of interventions; and 4) Explore key intervention characteristics and methodological characteristics and their association with reported effects, including coaching intervention duration, length of sessions, mode of delivery, and demographic variables.

Method

This systematic review and meta-analysis was reported following the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement [32]. The review protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO) database (CRD42021228567).

Search strategy and inclusion/exclusion criteria

To identify the relevant literature, a series of systematic searches was conducted on PsycINFO, Medline (Ovid) and the Web of Science. The searches were conducted using the keywords and their combinations. Medline key search terms included: "type II diabetes mellitus," "non-insulin dependent diabetes mellitus," "Diabetes Mellitus, Type 2/ or diabetes," "Coaching," "Health Coaching," and "personal coach*" (see Supplementary Material 1 for more details on Medline search strategy). A manual back chaining was utilised as an additional step to supplement the database searches find relevant literature. This involved examining the list of all the references in the included studies, including potential citations within each article and other relevant reviews.

The current review focused on people with T2DM (Population), who received health coaching (Intervention) and who were compared with a usual care or active control group (Comparison) on HbA1c levels (Outcome). Studies were only included if they were peer-reviewed RCTs, reported changes in HbA1c, published in English from January 1950 and April 2022, included participants aged 18 years or older and employed health coaching to influence T2DM. For the purpose of this review, health coaching was defined as using client-centred sessions in which the coach uses coaching skills and techniques to enable the client to engage and work toward their intended goals. The start date of searching was purposely selected to cover all coaching terms, such as health counselling, coaching, personal coaching, and health promotion in published studies from the emerging time of health coaching in the early 1950s. Articles were excluded if participants did not have a diagnosis of T2DM; were not subject to health coaching interventions; self-management was not the targeted behaviour;

included other variations of diabetes, e.g., gestational diabetes or type 1 diabetes mellitus; and HbA1c was not reported as an outcome measure. This review therefore included interventions that investigated the effectiveness of using the health coaching approach as a tool to impact the self-management of T2DM. Only RCT studies were included to explore effectiveness of the interventions and minimize the risk of bias [33].

Study selection and data extraction

Search results were initially screened against the inclusion criteria at title and abstract level. Full texts of these articles were screened next. Screening was completed independently by two researchers (AA, HH). The first author extracted data from the included studies, and then the second author reviewed the data for verification. Conflicts resolved by discussion between two reviewers (AA, HH). An independent reviewer (PN) conducted an additional step to double-check the extracted data. Data were systematically extracted using a prespecified extraction form (see Table 1 and Supplementary Material 2). Related studies (e.g., published protocols) were reviewed to extract further information. Relevant study information from the included articles was reviewed and data extracted (e.g., design, the theory or model used, BCTs, intervention structure, target behaviours, and outcome parameters) by two reviewers (AA, HH). The RCTs included were coded as to theories and BCTs used in the interventions as well as reported effects on glycaemic control. RCTs were also coded according to the modes of delivery, length and duration of the health coaching sessions.

Effect sizes (Cohen's *d*) [54] for the included interventions were calculated in line with recommended procedures for pretest-posttest-control group designs (i.e., RCTs with pre- and post- measures of the outcome variable) [55] which control for baseline differences in the outcome measure. In particular, baseline mean HbA1c values were subtracted from follow-up mean values for the intervention and control groups, separately, and these new values used to compute the effect size difference. Baseline standard deviations were used to estimate the pooled standard deviation to account for the fact that, *if* the intervention changes the outcome at follow-up, variation in outcome scores is likely to be greater in the intervention compared to control group. An Excel spreadsheet was created to calculate effect size differences following Morris' (16) formula based on data reported in the papers. Where baseline scores were not reported, effect sizes were based on follow-up scores using software available at www.psychometrica.de. The effect sizes were calculated so that positive effect sizes indicated greater reductions in HbA1c in the intervention group compared to the control group. As per Cohen's guidelines, the intervention has a small effect size when $d \geq 0.20$, a medium effect size when $d \geq 0.50$, and a large effect size when $d \geq 0.80$. Effect sizes of $d < 0.20$ were considered to be trivial.

Behaviour Change Technique (BCT) coding

The BCT taxonomy [25] was applied to the included studies to identify the use of BCTs. Two independent researchers (AA, HH) coded the intervention content reported in the methods section (intervention description) of each paper against the BCT taxonomy version 1 (BCTTv1), to identify the BCTs used in the health coaching interventions [25]. The coders followed the BCTTv1 guidance, for example, if a BCT was unclear (present or absent), it was coded as absent, as per the BCTTv1 guidance [25]. Both coders used Microsoft Excel (version 16.66.1) to generate a list of identified BCTs across all included interventions. Several discussion meetings were held to discuss the BCTs identified and to resolve any disagreements regarding the coded BCTs until reaching an agreement. A third independent reviewer (PN) was involved to confirm consensus decisions.

Meta-analytic strategy

Meta-Essentials version 1.5 [56] was used to compute the sample-weighted average effect (Hedges g_+) of the health coaching interventions on HbA1c scores. Cochrane's Q was used to test whether the effect sizes were heterogeneous and the I^2 statistic was used to assess the proportion of the variance in the effect sizes explained by any heterogeneity. Moderator analyses were then conducted to identify variables that accounted for any variability in effect sizes. For categorical moderators (e.g., presence or absence of a BCT) average effect sizes were calculated for each level of the moderator. The difference between the effect sizes was assessed using the Q statistic. The significance of continuous moderators was tested using meta-regression (see Tables 2 & 3).

Publication bias was assessed through visual inspection of the funnel plot (i.e., lack of asymmetry in the distribution of the studies) and Egger's regression.

Study quality

The Cochrane collaboration tool was used to assess the quality of the included studies [57].. Each study was rated based on specific criteria related to the quality of its methods and reporting, selection, performance, detection, attrition, reporting, and other biases. The assessment of study quality was evaluated by three reviewers (AA,EG,SC). See Table 4 and Fig. 2 for further details.

Table 1 Description of included studies in the systematic review

Study, Country, and Objectives	Sample (completed), Mean Age; Female %	Study Duration (M) (Intervention+ Follow-ups)	Delivery mode	Intervention providers	Measurements (n)	Results	Control group
Frosch et al. (2011), U S[34] To assess participants' improvement in self-care behaviours, level of HbA1C, lipid and BP levels at 6 months	201 (201); 55.5; 48.5	6	TEL	Nurse educators	(3), A1c, lipid and blood pressure	Decline in HbA1c at 6 months in both groups ($P < 001$),	Educational brochure
Glasgow et al. (2006), U S[35] To assess the impact of a computer-assisted intervention on T2DM self-management	335 (299); 61.5; 50.2	2	FTF,TEL,ERPM/EA	Health educators	(7) FVSS, Daily fat intake, HbA1c, Cholesterol, PHQ, DDS, BMI	There was a decline in HbA1c favouring intervention group, but these differences did not reach significance	Computer-enhanced, Usual care
Kim et al., (2015), U S[36] To assess effectiveness of a community-based, culturally tailored, program in T2DM patients	250 (209); 58.7; 43	12	TEL, GER	Nurses and community health workers	(8) HbA1c, Triglyceride, Cholesterol, Blood pressure, diabetes-related quality of life, self-efficacy, adherence to diabetes management regimen, and health literacy	The difference between the two groups was statistically significant favouring the intervention group (reductions in HbA1c: 1 .0–1.3% compared to the control group with reductions of 0.5–0.7%)	Educational brochure
McKay et al. (2002), U S[37] To assess the impact of using an internet-based in improving diabetes self-management	160 (133); 59.3; 53.1	3	ERPM/EA	Health coach	(6) HbA1c, Fat intake, Poor dietary practices, Depression symptoms, Psychological well-being (SF-12), Total cholesterol	There was an improvement but not statistically significant difference favouring coaching group in relation to HbA1c	Information- only reading
Ruggiero et al. (2010), U S[38] To assess the effect of the intervention delivered by medical assistant coach on HbA1C compared with usual care group	50 (42); 65.8; 66	6	FTF,TEL	Medical assistants	HbA1c	HbA1C level decreased across the intervention group (MAC), but it was not significant between groups	Treatment as usual

Table 1 (continued)

Study, Country, and Objectives	Sample (completed), Mean Age; Female %	Study Duration (M) (Intervention+ Follow-ups)	Delivery mode	Intervention providers	Measurements (n)	Results	Control group
Sacco et al. (2009), U S[39] To evaluate the effects of telephone-bases coaching provided by professionals on T2DM, including diabetes adherence and control, diabetes-related complications, and diabetes distress	62 (48); 52; 58	6	TEL	University students	(9) HbA1c, Diet, Exercise, Foot care, Depression, Self-efficacy, HTS, RSC, ASC	HbA1C decreased in the coaching group (M = 7.4%; SD = 1.12), but was not statistically significant	Usual Care
Thom et al. (2013), U S[40] To determine how clinic-based peer health coaching affects the management of uncontrolled T2DM in low-income populations	299 (236); 55.2; 52	6	FTF,TEL	Peers	(4) HbA1c, BMI, LDL, SBP	The difference was statistically significant between the two groups favouring the coaching group (HbA1C decreased by 1.07%) Whereas the reduction was 0.3% in the control group	Usual Care
Whittemore et al. (2004), U S[41] To assess the effect nurse-coaching intervention on T2DM	53 (49); 57.6; 100	6	FTF,TEL,ERPM/EA	Nurses	(5) HbA1C, BMI, Dietary, Exercise, Distress	A difference between the two groups was documented at 3 months in HbA1C levels favouring the coaching group, but the difference was not statistically significant	Usual Care
Willard-grace et al. (2015), U S[42] To assess impacts of health coaching in the control of T2DM, Hypertension, and Hyperlipidemia compared with usual care	144 (132); NA; NA	12	FTF, TEL	Medical assistants	(4) HbA1c, HDL, LDL, SBP	Intervention group was as twice as many patients in control arm achieved the HbA1c goal (48.6% vs 27.6%, $P = .01$). The difference was statistically significant	Usual Care
Wolever et al. (2010), U S[43] To evaluate the impact of integrative health coaching on various T2DM patient variables	56 (49); 53; 77	6	TEL	Psychologist and social worker	(10) HbA1c, ASK-20, MAS; PAM; ADS, BFS, ISEL-12, PSS-4, SF-12, Exercise	HbA1c was reduced in the intervention group significantly by 0.64% (from 8.9 1.78% at baseline to 8.3 1.76%; $P = .030$; Cohen $d = .34$).	Usual Care

Table 1 (continued)

Study, Country, and Objectives	Sample (completed), Mean Age; Female %	Study Duration (M) (Intervention+ Follow-ups)	Delivery mode	Intervention providers	Measurements (n)	Results	Control group
Chen et al., (2016), Taiwan [44] To evaluate changes in HbA1c for group provided care by pharmacist compared usual care without a pharmacist	100 (100); 72.5;50	6	FTF,TEL	Certified diabetes educator Pharmacist	(1), Change in A1c level (6 months)	HbA1c level significantly decreased (0.83%) for the intervention group with an increase of 0.43% for the usual care arm ($P \leq 0.001$).	Usual Care
Lin et al., (2021), Taiwa n[45] To explore the impact of health coaching on A1c and diet for patients with T2DM	114(114)45;49	6	FTF, TEL	Health Coach	(8) HbA1c, Daily calorie intake, Whole grains, Meats and protein, Milk and dairy products, Vegetables, Fruits, Fats and oils	Patients with type 2 diabetes who underwent a 6-month health coaching program saw a significant reduction in HbA1c by 0.62% ($P < 0.01$)	Usual care
Basak Cinar & Schou (2014), Turkey [46] To assess the difference in outcomes between health coaching group compared with usual health education for T2DM	186 (162[a]); NA; NA 100	16 M (10+ 6)	FTF, TEL	Dental professional	(3), HbA1C, CAL and TBSES	Significant differences found for HbA1C in Health coaching group, ($P < 0.05$)	Health education
Sherifali et al., (2021), Canad a[47] To assess the impact of telephone health coaching on A1c for patients with T2DM	365(365) 57;50	12 M (6+6)	TEL	Registered nurse/certified diabetes educator	(2) HbA1c, ADDQoL-19	HbA1c was reduced in the intervention group significantly by 1.78% ($P < 0.005$)	Usual diabetes education
Cho et al. (2011), Kore a[48] To assess impact of health coaching on HbA1c improvement after 3 months	71 (64); 64.2; NA	3	FTF, ERPM	Physicians and nurses	(2), HbA1c, cholesterol	HbA1c level was significantly decreased for intervention group (reduced from 8.0 to 7.5%) $P < 0.0$. In control group HbA1c reduced from 8.0 to 7.8%, $P = 0.11$)	Diabetes education

Table 1 (continued)

Study, Country, and Objectives	Sample (completed), Mean Age; Female %	Study Duration (M) (Intervention+ Follow-ups)	Delivery mode	Intervention providers	Measurements (n)	Results	Control group
Holmen et al. (2014), Norway [49] To assess effectiveness of using phone-based self-management system used by a diabetes specialist on HbA1c, diabetes self-management, and improvement in quality of life	151 (120); 57.0; 41	12 M(4+ 8)	TEL,ERPM/EA	T2DM specialist nurse	(9) HbA1c, BMI, PAEL, HAD, STA CAASMI, HSN, SIS, EWB	All groups have a reduction in HbA1c level	Usual care
Karhula et al. (2015), Finland[50] To assess effectiveness of phone-based health coaching program, on improvement in HRQL and other clinical measures of T2DM and heart disease patients	250 (217); 66.3; 44.4	12	TET,ERMP/EA	Health coaches	(8), HbA1c, BP, BMI, Waist circumference, Triglycerides, Cholesterol, LDL, HDL	No statistically significant difference found in relation to HbA1c between the two groups	Usual care
Kempf et al. (2017), Germany[51] To assess effectiveness of the Telemedical Lifestyle intervention Program (TeLiPro) on HbA1c	202(167/133);59.6;49	12 M(3 + 9)	TEL,ERPM/EA	Diabetes coaches	(6), HbA1c, BMI, CVD, QoL, eating behaviour, Antidiabetic medication	The difference between the two groups was statistically significant favouring the TeLiPro group in relation to HbA1c (mean ± SD - 1.1 ± 1.2%, $P < 0.0001$)	Usual Care
Odnoletkova et al. (2016), Belgium[52] To test the effectiveness of telecoaching intervention on HbA1c with T2DM	574 (486); 63.1; 38.5	18 M (6+ 12)	TEL	Nurse educator	(9) HbA1c, total cholesterol, LDL cholesterol, HDL cholesterol, Triglycerides, Systolic blood pressure, Diastolic blood pressure, BMI, Weight	The difference in the means between the two groups was statistically significant favouring the coaching group.	Usual Care
Varney et al. (2014), Australia[53] To evaluate the health coaching intervention's long-term efficacy	94 (71); 64.1; 31.9	12 M (6+6)	TEL	Registered dietician	(13) HbA1C, Fasting glucose, cholesterol LDL cholesterol, HDL cholesterol, Triglyceride, Systolic BP, Diastolic BP, Weight, BMI, Waist circumference Physical activity, K10 depression score	Significant effects were observed between groups at 6 months in relation to HbA1C (reductions in A1C up to 0.8%)($P = 0.03$)	Usual Care

ERPM/EA electronic remote patient monitoring/electronic assistance, *FTF* face to face, *GRP* group, *TEL* telephone, *CAL* clinical attachment loss, *TBSES* tooth-brushing self-efficacy, *FVSS* Fruit and Vegetable Screener score, *SF-12* Short-Form Health Survey, *PHQ* Patient Health Questionnaire, DDS Diabetes Distress Scale, *PAEL* Positive and active engagement in life, *HAD* Health-directed activity, *STA* Skill and technique acquisition, *ADS* Appraisal of Diabetes Scale, *HDL* High-density lipoprotein, *CAASMI* Constructive attitudes and approaches Self-monitoring and insight, *ISEL-12* Interpersonal Support Evaluation List, *HSN* Health service navigation, *SIS* Social integration and support, Emotional well-being EWB, *LDL* Low-density lipoprotein, *HTS* Healthcare team support, *RSC* Reinforcement for self-care, *ASC* Awareness of self-care goals, *ASK* Adherence Starts with Knowledge, *MAS* Morisky Adherence Scale, *PAM* Patient Activation Measure,), *BFS* Benefit-Finding Scale, *PSS-4* Perceived Stress Scale, *ADDQoL-19* 19-item Audit of Diabetes-Dependent Quality of Life scale

Table 2 Sample-weighted Average Effect Sizes (ES) for Interventions Including vs. Excluding Specific BCTs

BCT No.	BCT	*k*	g_+ present (95% CI)	g_+ absent (95% CI)	Q for difference	*p*
1.1	Goal setting (behaviour)	13	0.26 (0.12, 0.41)	0.33 (0.18, 0.47)	0.38	0.538
1.2	Problem solving	10	0.19 (0.07, 0.30)	0.37 (0.21, 0.52)	3.51	0.061
1.3	Goal setting (outcome)	7	0.35 (0.25, 0.45)	0.25 (0.11, 0.40)	1.01	0.315
1.4	Action planning	8	0.25 (0.08, 0.42)	0.32 (0.18, 0.46)	0.44	0.506
1.5	Review behaviour goal(s)	3	0.20 (−0.25, −0.64)	0.31 (0.21, 0.42)	0.37	0.545
1.6	Discrepancy between current behaviour and goal	2	0.46 (−0.09, 1.00)	0.27 (0.17, 0.38)	0.42	0.519
1.7	Review outcome goal(s)	1	–	–	–	–
1.8	Behavioural contract	1	–	–	–	–
2.1	Monitoring of behavior by others without feedback	1	–	–	–	–
2.2	Feedback on behaviour	1	–	–	–	–
2.3	Self-monitoring of behaviour	3	0.22 (−0.28, 0.73)	0.29 (0.19, 0.39)	0.06	0.808
2.4	Self-monitoring of outcome(s) of behaviour	5	0.23 (−0.05, 0.52)	0.30 (0.19, 0.41)	0.18	0.672
2.5	Monitoring of outcome(s) of behavior without feedback	1	–	–	–	–
2.6	Biofeedback	5	0.18 (−0.11, 0.46)	0.32 (0.22, 0.42)	0.82	0.365
2.7	Feedback on outcome(s) of behaviour	4	0.28 (−0.03, 0.58)	0.29 (0.18, 0.40)	0.00	0.951
3.1	Social support (unspecified)	8	0.30 (0.14, 0.45)	0.28 (0.13, 0.43)	0.02	0.884
3.3	Social support (emotional)	2	0.33 (0.12, 0.55)	0.29 (0.17, 0.40)	0.11	0.746
4.1	Instruction on how to perform a behaviour	1	–	–	–	–
8.7	Graded tasks	1	–	–	–	–
9.1	Credible source	5	0.08 (−0.04, 0.19)	0.34 (0.22, 0.46)	**7.67****	**0.006**
10.4	Social reward	3	0.01 (−0.20, 0.22)	0.32 (0.21, 0.43)	**3.92***	**0.048**
12.5	Adding objects to the environment	1	–	–	–	–
13.2	Framing/reframing	2	0.10 (−0.35, 0.54)	0.31 (0.20, 0.42)	0.82	0.365

Results

Search Results

The search results yielded 1163 titles and abstracts through Medline, PsycINFO and the Web of Science. There were 145 full-text studies checked for eligibility and a total of 20 RCTs met inclusion criteria (see Fig. 1) [32].

Meta-analytic Results

Meta-analysis of 20 effect sizes from 20 unique studies, with a total sample of 3222 participants, indicated that, on average, health coaching interventions for T2DM have a small but statistically significant (positive) effect on reducing HbA1c ($g_+ = 0.29$, 95% CI: 0.18 to 0.40). Visual inspection of the funnel plot suggested that there was no asymmetry in the distribution of the studies and no risk of publication bias. Egger's regression was also non-significant ($p = 0.730$), indicating lack of publication bias.

The effect sizes (d) of interventions ranged from d = −0.05 to d = 0.78. None of the interventions had a large effect size [44], and only three had a medium effect size (d = 0.71 to d = 0.78) [42, 45, 51, 53]. The remaining 17 interventions had small (d ≥ 0.20) [36, 38–40, 43, 46–49, 52] or trivial (d < 0.20) effect sizes [34, 35, 37, 41, 50]. Cochrane's *Q* was statistically significant ($Q = 36.68$, $p = .009$) suggesting that the effect sizes were heterogeneous and the I^2 statistic indicated that a proportion of the variance in the effect sizes was explained by this heterogeneity ($I^2 = 48.20\%$), which indicates a need for moderation analysis to identify variables that account for the variability.

Study Characteristics

Table 1 reports the characteristics of included studies for both interventions (health coaching), and control groups (usual care), including sample size, mean age of participants, intervention duration, personnel, and mode of delivery (e.g., face-to-face, telephone-based, web-based). The included studies comprised 20 RCTs published between 1950 and 2022. A total of 3222 participants were included in the 20 studies, of whom 1674 were randomised to receive coaching interventions and 1548 were allocated to control groups. The majority of studies ($n = 10$) were conducted in the US [34–43], two were conducted in Taiwan [44, 45], and the rest were conducted once in different countries including Turkey [46], Canada [47], South Korea [48], Norway [49], Finland [50], Germany [51], Belgium [52], and Australia [53]. In the 17 studies that reported gender of participants, 53% of participants were female. The mean age of the recruited participants was 59.3 (SD = 6.2). Due to the

Table 3 Moderators of the Effect of Health Coaching Interventions for T2DM: Sample-weighted Average Effect Sizes (ES)

						Categorical	**Continuous**		
Moderators	*N*	*k*	Levels of the moderator	*Q*	*p*	*g* + (95% CI)	*β*	SE	*p*
Sample moderators									
Age (in years)	2928	18					0.19	0.01	0.442
Gender (percentage of females)	2857	17					−0.13	0.00	0.603
Methodological moderators									
Number of BCTs used	3222	20					−0.36	0.02	0.107
Study length	3222	20					0.14	0.01	0.535
Intervention length	1366	6					−0.04	0.05	0.916
Follow-up length	1366	6					−0.25	0.05	0.574
Type of control group	3222	20		0.69	0.406				
	1078	6	Active control			0.24 (0.10, 0.37)			
	2144	14	Usual care			0.32 (0.417, 0.46)			
Type of intervention provider	3222	20		1.24	0.538				
	2182	12	Healthcare professional			0.25 (0.10, 0.39)			
	568	4	Coaches			0.36 (0.06, 0.65)			
	472	4	Assistants/students			0.37 (0.25, 0.48)			
Mode of Delivery	3222	20		1.17	0.556				
	1275	6	Telephone only			0.23 (0.05, 0.42)			
	1134	8	Telephone & FtF			0.36 (0.20, 0.51)			
	813	6	Other combinations			0.25 (0.01, 0.48)			
Primary outcome measure	3222	20		**4.20***	**0.040**				
	2750	16	HbA1c			0.32 (0.20, 0.45)			
	472	4	Others			0.10 (0.03, 0.17)			
Theory use in intervention development	3222	20		1.34	0.247				
	2532	14	Used			0.24 (0.16, 0.32)			
	690	6	Not used			0.43 (0.15, 0.72)			
MI theory use	3222	20		0.23	0.632				
	2108	9	Used			0.26 (0.15, 0.37)			
	1114	11	Not used			0.32 (0.14, 0.50)			

inconsistent reporting of other demographic and socio-economic characteristics, such as education, ethnicity and income status, across the 20 papers we were unable to report them here. The recruitment of participants was varied and drawn from different communities including ethnic community centres [36], community health centres [34, 48, 49], community advertisement [43, 47, 49, 51], primary care or hospital clinics [38, 41, 45, 46, 53] and databases [40, 44, 50, 52]. For clinical factors, including HbA1c, there were no discernible changes between the intervention and control groups at baseline. The mean HbA1c level across all studies at baseline was 8.42% (SD = 0.78). The reduction in HbA1c found to be clinical significant in eight studies [36, 40, 42–44, 46, 47, 51] (decrease of ≥5 mmol/mol)[58].

Moderation analysis of the sample characteristics indicated that intervention effectiveness was not related to age ($\beta = 0.19$, $p = 0.442$) or gender ($\beta = -0.13$, $p = 0.603$). Moderation analysis of the study characteristics indicated that only the type of primary outcome measure was significantly related to intervention effectiveness ($Q = 4.20$, $p = 0.040$), such that studies including HbA1c as the primary outcome ($g_+ = 0.32$, $k = 16$) were more effective than studies with other primary outcomes ($g_+ = 0.10$, $k = 4$).

Mode of delivery and intervention duration

Health coaching was delivered through various methods including exclusive telephone-based [34, 39, 43, 47, 52, 53], exclusive web or mobile-based remote patient monitoring/electronic assistance (ERPM/EA) systems [37] or in combinations of face-to-face and telephone-based [36, 38, 40, 42, 44–46]; face-to-face and ERPM/EA[48] telephone-based and ERPM/EA [49–51] or face-to-face, telephone-based and ERPM/EA [35, 41]. The duration of studies ranged from two [37] [48] to 18 months [52] (*Mdn* = 6 months). Only six studies reported separate figures for intervention and follow-up durations,

Table 4 Risk of bias assessments based on the Cochrane collaboration tool

	Random sequence generation (Selection Bias)	Allocation concealment (Selection bias)	Blinding of participants and personnel (Performance bias)	Blinding of outcome assessment (Detection bias)	Incomplete outcome data (Attrition bias)	Selective reporting (Reporting bias)	Other sources of bias (Other bias)
Frosch et al. (2011), U S[34]	Low	Low	High	High	Low	Low	Unclear
Glasgow et al. (2006), U S[35]	Unclear	unclear	Unclear	Unclear	Low	Low	High
Kim et al., (2015), U S[36]	Unclear	Unclear	High	Low	Low	Low	Unclear
McKay et al. (2002), U S[37]	Unclear	Unclear	Unclear	Low	Low	Low	Unclear
Ruggiero et al. (2010), U S[38]	Unclear	Unclear	Unclear	High	Low	Low	High
Sacco et al. (2009), U S[39]	Low	Unclear	Unclear	Low	Low	Low	Unclear
Thom et al. (2013), U S[40]	Unclear	Low	Unclear	Low	Low	Low	Unclear
Whittemore et al. (2004), U S[41]	Unclear	unclear	Unclear	unclear	Low	Low	High
Willard-grace et al. (2015), U S[42]	Low	Low	High	Unclear	Low	Low	Unclear
Wolever et al. (2010), U S[43]	Unclear	unclear	low	low	Low	Low	High
Chen et al., (2016), Taiwa n[44]	Low	low	Unclear	low	low	low	Unclear
Lin et al., (2021), Taiwa n[45]	Low	low	low	Unclear	low	low	Unclear
Basak Cinar & Schou (2014), Turke y[46]	Unclear	unclear	High	High	low	Low	Unclear
Sherifali et al., (2020)[47]	Low	low	Unclear	Unclear	Low	Low	Low
Cho et al. (2011), Kore a[48]	Unclear	unclear	unclear	High	Low	Low	Unclear
Holmen et al. (2014), Norwa y[49]	Low	Unclear	High	Low	Low	Low	Unclear
Karhula et al. (2015), Fin-land,[50]	Low	Low	Unclear	Low	Low	Low	Unclear
Kempf et al. (2017), German y[51]	Low	Low	Low	Low	Low	Low	Low
Odnoletkova et al. (2016), Belgiu m[52]	Low	Low	Unclear	Low	Low	Low	Unclear
Varney et al. (2014), Australi a[53]	Low	Low	High	High	Low	Low	High

with intervention duration ranging from three [51] to 10 months [46] (*Mdn* = 6 months) and the duration of follow-ups ranging from six [46] to 12 months [52] (*Mdn* = 7 months). Mode of delivery ($Q = 1.17$, $p = 0.556$) and the duration of study ($\beta = 0.14$, $p = 0.535$), intervention ($\beta = -0.04$, $p = 0.916$) and follow-up ($\beta = -0.25$, $p = 0.574$) were not significantly related to intervention effectiveness (see Table 3).

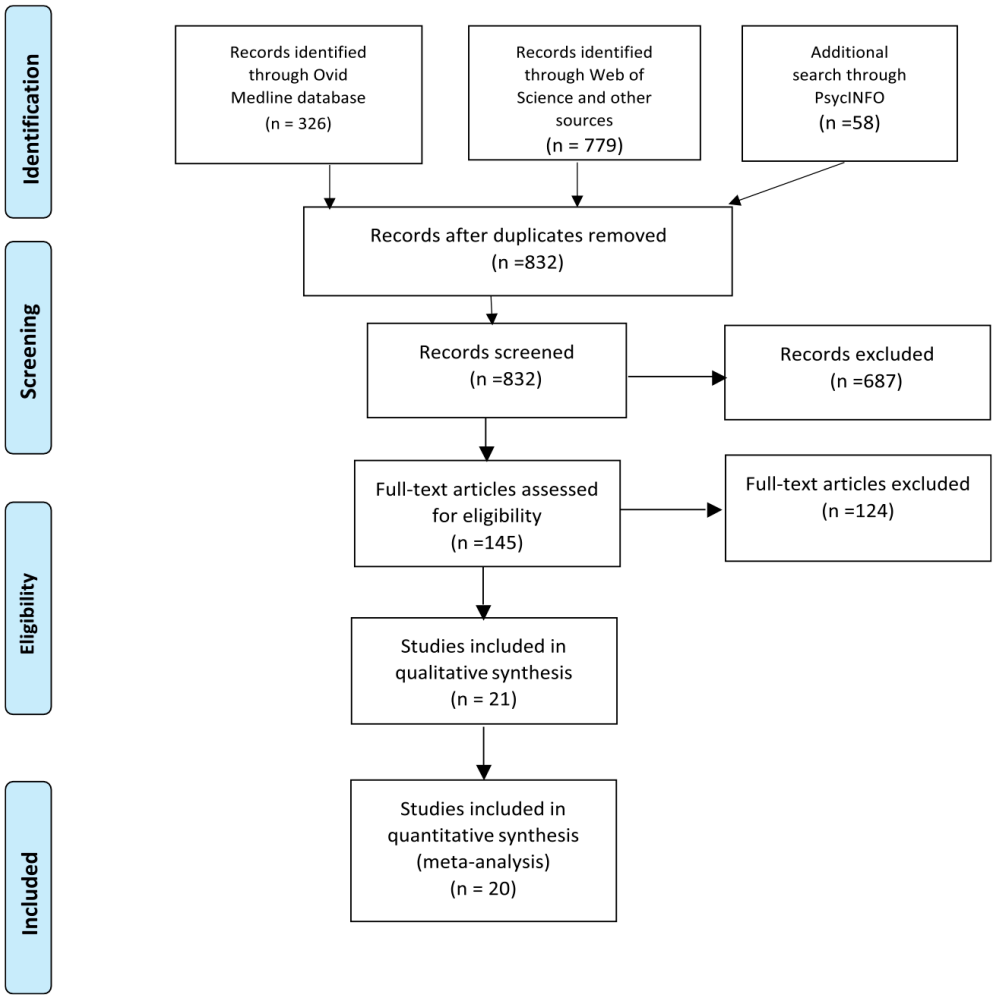

Fig. 1 PRISMA Flow Diagram Showing Study Selection Process

Delivery personnel

Different people delivered the health coaching interventions. In four studies, the health coaching intervention was delivered by untrained personnel [34, 41, 44, 46, 53], while the remaining 16 interventions reported training of the interventionist on health coaching. Seven studies relied on nurses to deliver coaching sessions [34, 36, 47–49, 52], four studies provided interventions by trained health coaches [35, 37, 50, 51], and only one study was delivered by health coaches certified by the International Coach Federation (ICF) [45]. The remaining interventions were delivered by different professionals, including dental care providers [46], community health workers [36], dieticians [53], medical staff [38, 42], pharmacists [44], psychologists [43], college students [41], peer patients [40], and physicians [48]. Type of intervention provider was not significantly related to intervention effectiveness ($Q = 1.24$, $p = 0.538$) (see Table 3).

Behavioural framework and theory use

The heterogeneity of interventions was evident in relation to the employed approaches and underpinning theories. Out of the 20 papers, five studies did not report the use of theories [34, 37, 44, 48, 51, 53]. The remaining 15 were grounded in different theories or frameworks. Most studies employed motivational interviewing [35, 36, 40, 42, 45–47, 49, 52], two studies used the transtheoretical model [38, 49], and self-efficacy theory, cognitive-behavioural therapy and social-cognitive theory were each used once [39, 46]. The use of theory was not significantly related to intervention effectiveness ($Q=1.34$, $p=0.247$), nor was the specific use of MI ($Q=0.23$, $p=0.632$) (see Table 3).

Identified BCTs

A total of 23 BCTs were identified across the 20 studies reviewed (see Table 5). Interventions were varied in terms of the number of BCTs that were utilized in each intervention, ranging from 0 to 9 BCTs. The median of BCTs used across all interventions was 5. The most frequently coded BCT was 1.1 *goal setting (behaviour)*, which has identified in 13 interventions [34–36, 38–41, 45, 46, 49–51]. 1.2 *problem solving* was the second most commonly identified BCT, reported in 10 interventions [35–39, 41, 43, 49, 52, 53]. Two BCTs, *1.4 action plan* [34, 35, 39, 40, 45, 46, 50, 53] and *3.1 social support (unspecified)* [35, 37–39, 44, 45, 47, 48], were each reported in eight studies. *1.7 review outcome goals, 1.8 behavioural contract, 2.2 feedback on behaviour, 4.1 instruction on how to perform a behaviour, 8.7 graded tasks, 12.5 adding objects to the environment, and 2.5 monitoring outcome(s) of behaviour by others without feedback* were each used once in six interventions [37, 39, 46, 48, 52, 53]. No BCTs were identified in one study [42].

BCTs and intervention effectiveness

An overview of the use of different BCTs and effect sizes found in each study is presented in Table 5. The most effective intervention based on the effect size (d = 0.78) used only one BCT: *3.1 social support (unspecified)* [44]. Only one BCT, 1.1 *goal setting (behaviour,)* was used across all the interventions with a medium effect size, although it was also the most commonly used BCT across interventions with small or trivial effects.

There was no evidence of an association between the number of BCTs used in an intervention and its effect size ($\beta=-0.11$, $p=0.651$) (see Table 2). Of the moderation analysis with 23 different BCTs identified, only two analysis yielded significant results. Specifically, interventions that used *credible sources* of information (BCT 9.1) (Hedges' $g_+=0.08$, $k=5$) were significantly less effective than interventions that did not use this BCT (Hedges' $g_+=0.34$, $k=15$; $Q=7.67$, $p=0.006$). In addition, interventions that used *social reward* (BCT 10.4) (Hedges' $g_+=0.01$, $k=3$) were significantly less effective than interventions that did not use this BCT (Hedges' $g_+=0.32$, $k=17$, $Q=3.92$; $p=0.048$).

Quality of the included studies

Although some studies showed good methodological quality due to their low bias [44, 45, 50–52], the majority were weak because of either high or unclear risk of bias [34, 35, 37–43, 46–49, 53]. Eleven of the 20 studies [34, 39, 42, 44, 45, 47, 49–53] described the method of randomization generation and 10 studies [34, 40, 42, 44, 45, 47, 50–53] used a concealed allocation schedule. The methodological quality of blinding participants and personnel on the assignment of participants to study groups were generally low due to either high or unclear bias in procedures across most studies and insufficient detail. Across all the included studies, attrition bias and selective outcome reporting bias were low and not detected. Table 4 and Fig. 2 provide further details about the quality of the included studies.

Discussion

This review sought to identify and investigate the use of BCTs in health coaching interventions for T2DM. The included health coaching interventions were varied in their designs, including intervention duration, session length, intervention providers, theoretical basis, BCTs utilised and delivery modality. Overall, the meta-analysis indicated that health coaching had a significant small-sized effect ($g_+=0.29$) on blood glucose control. Studies that included HbA1c as the primary outcome had larger effect sizes indicating the benefit of a close correspondence between the main target of the intervention and the primary outcome.

Our meta-analysis found no advantage to utilizing one particular delivery method over others. Furthermore, no specific length of health coaching session was associated with a better outcome, although a previous,study suggested that greater time spent in coaching sessions may result in more effective result s[47]. Other studies suggest that the coaching session's length should be framed according to the complexity of the condition presented by participants [41, 46]. Given that the conflicting pattern of findings, further research is needed to directly compare different durations of health coaching.

Interventions were delivered by different personnel, ranging from trained undergraduate students [39] to certified professional health coaches [45]. Only five out of 20 included studies relied on trained health coaches to deliver the interventions [35, 37, 45, 50, 51] while the rest were

Table 5 Behaviour Change Techniques (BCTs) used in each intervention

	Effect size	*Underpinning Theory*	*1.1goal setting (behaviour)*	*1.2 problem-solving*	*1.3 goal-setting (outcome)*	*1.4 action planning*	*1.5 review behaviour goal(s)*	*1.6 Discrepancy between current behavior and goal*	*1.7 Review outcome goals*	*1.8 behavioural contract*	*2.1 monitoring of behaviour by others without feedback*	*2.2 feedback on behaviour*	*2.3 Self-monitoring of behaviour*
Frosch et al. (2011), U S [34]	− 0.05	NA	X			X	X						
Glasgow et al. (2006), U S [35]	0.062	MI, CCM, SCT	X	X		X	X						
Kim et al. (2015), U S [36]	0.292	MI, PPM	X	X	X								
McKay et al. (2002), U S [37]	0.14	NA		X									
Ruggiero et al. (2010), U S [38]	0.259	TTM	X	X									
Sacco et al. (2009), U S [39]	0.172	CBT	X	X		X		X	X				
Thom et al. (2013), U S [40]	0.383	MI	X			X							
Whittemore et al. (2004), U S [41]	0.098	ACI	X	X	X								
Willard-Grace et al. (2015), U S [42]	0.478	CCM, MI											
Wolever et al. (2010), U S [43]	0.253	DIM		X	X								
Chen et al. (2016), Taiwan [44]	0.78	NA											
Lin et al., (2021), Taiwan [45]	0.462	MI	X		X	X					X		

Table 5 (continued)

	Effect size	Underpinning Theory	1.1goal setting (behaviour)	1.2 problem-solving	1.3 goal-setting (outcome)	1.4 action planning	1.5 review behaviour goal(s)	1.6 Discrepancy between current behavior and goal	1.7 Review outcome goals	1.8 behavioural contract	2.1 monitoring of behaviour by others without feedback	2.2 feedback on behaviour	2.3 Self-monitoring of behaviour
Basak Cinar and Schou (2014), Turkey [46]	0.383	MI, SET	X		X	X							
Sherifali et al., (2021), Canada [47]	0.31	MI			X								
Cho et al. (2011), Korea [48]	0.328	NA										X	
Holmen et al. (2014), Norway [49]	−0.167	MI, TTM	X	X									X
Karhula et al. (2015), Finland [50]	0.087	PTM	X			X							X
Kempf et al. (2017), Germany [51]	0.713	NA	X										X
Odnoletkova et al. (2016), Belgium [52]	0.19	CF,MI, PPM		X									
Varney et al. (2014), Australia [53]	0.729	NA	X	X	X	X	X	X		X			
n(%)			13 (65)	10 (50)	7 (35)	8 (40)	3 (15)	2 (10)	1 (5)	1 (5)	1 (5)	1 (5)	3 (15)

Table 5 (continued)

	2.4 self-monitoring of outcome(s) of behaviour	*2.5 monitoring outcome(s) of behaviour by others without feedback*	*2.6 biofeedback*	*2.7 feedback on outcome(s) of behaviour*	*3.1 social support (unspecified)*	*3.3 social support (emotional)*	*4.1 instruction on how to perform a behaviour*	*8.7 Graded tasks*	*9.1credible sources*	*10.4 social reward*	*12.5 adding objects to the environment*	*13.2 framing/ reframing*	# of Used BCTs
Frosch et al. (2011), U S [34]									X				4
Glasgow et al. (2006), U S [35]			X	X	X				X				8
Kim et al. (2015), U S [36]	X											X	5
McKay et al. (2002), U S [37]	X		X	X	X				X		X		7
Ruggiero et al. (2010), U S [38]					X								3
Sacco et al. (2009), U S [39]				X	X			X		X			9
Thom et al. (2013), U S [40]						X							3
Whittemore et al. (2004), U S [41]						X				X			5
Willard-Grace et al. (2015), U S [42]													0
Wolever et al. (2010), U S [43]									X				3
Chen et al. (2016), Taiwan [44]					X								1
Lin et al., (2021), Taiwan [45]					X								5

Table 5 (continued)

	2.4 self-monitoring of outcome(s) of behaviour	*2.5 monitoring outcome(s) of behaviour by others without feedback*	*2.6 biofeedback*	*2.7 feedback on outcome(s) of behaviour*	*3.1 social support (unspecified)*	*3.3 social support (emotional)*	*4.1 instruction on how to perform a behaviour*	*8.7 Graded tasks*	*9.1credible sources*	*10.4 social reward*	*12.5 adding objects to the environment*	*13.2 framing/ reframing*	# of Used BCTs
Basak Cinar and Schou (2014), Turkey [46]		X											4
Sherifali et al., (2021), Canada [47]					X								2
Cho et al. (2011), Korea [48]					X				X				3
Holmen et al. (2014), Norway [49]	X		X							X		X	7
Karhula et al. (2015), Finland [50]	X		X										6
Kempf et al. (2017), German y [51]	X		X	X									5
Odnoletkova et al. (2016), Belgium [52]							X						7
Varney et al. (2014), Australia [53]													7
n(%)	5 (25)	1 (5)	5 (25)	4)20)	8 (40)	2 (10)	1 (5)	1 (5)	5 (25)	3 (15)	1 (5)	2 (10)	

MI Motivational interviewing, *SET* self-efficacy theory, *CCM* chronic care model, *SCT* social cognitive theory, *TTM* transtheoretical model, *TM* Pfizer's telecoaching model, *PPM* PRECEDE–PROCEED mode, CF Coach framework, *CBT* Cognitive behavioural therapy, *ACI* Adaptation to chronic illness, *DIM Duke integrative medicine*

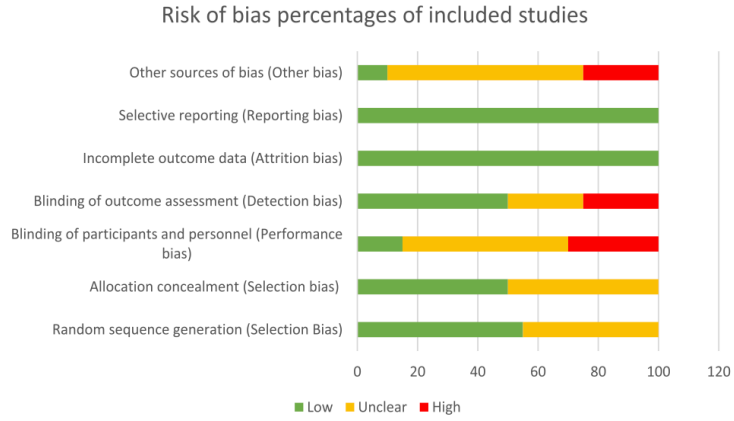

Fig. 2 Risk of bias of included studies

provided by people with different backgrounds including community healt h[36], dentistry [46], nutritio n[53], medicine [38, 42, 48], nursing [34, 36, 41, 48, 49, 52], pharmac y[44], psychology [43] social science [43], undergraduate student s[39], and patients' peers [40]. This diversity may explain why coaching protocols are inconsistent or unstandardised, contributing to intervention variation and unpredictable outcomes, although the results of the meta-analysis indicated that they type of personnel delivering the health coaching did not impact on outcomes.

Theory-based interventions can lead its providers to identify the target behaviours and strategies needed to achieve desired outcomes. Half of the health coaching interventions used motivational interviewing (48%) [35, 36, 40, 42, 45–47, 49, 51, 52]. Using motivational interviewing as an intervention theoretical basis may help in understanding participants' triggers for change and addressing their ambivalence, which is the essential goal of health coaching. Although prior studies' findings [18, 59], suggested that employing motivational interviewing might produce better results for behaviour change, our meta-analysis findings revealed no such effect.

Considering the use of BCTs in the heath coaching interventions, we found that 19 of 20 included studies used different BCTs, with a mean of 4.5 BCTs being identified in each intervention. Although 11 of the included studies were published after the BCTTv1 was released in 2013, none explicitly reported BCTs. Out of 23 identified BCTs, only two BCTs, *goal-setting (behaviour) and problem-solving,* were commonly used across different health coaching programs with T2DM. These two BCTs have been previously identified as key ingredients for behaviour change [60], and T2DM self-management programs [29]. However, being used frequently does not imply that these BCTs contribute to improving the interventions and self-management goals [61]. For instance, the intervention with smallest effect size [34] ($d = -0.05$) used more BCTs compared to the intervention with the largest effect size [44] ($d = 0.78$). Moreover, the meta-analysis findings failed to find any evidence linking the use of specific BCTs to greater intervention effectiveness, although most of the comparisons were based on very few studies where the BCT is present. As a result, there's a possibility of both type 1 and type 2 errors. For example, the finding that interventions that included the BCT *social reward* had a smaller average effect size compared with studies where the BCT was absent was only based on three studies that included this BCT. In contrast, the BCT *discrepancy between current behaviour and goal,* which was found to have the largest largest effect, was not found to be a significant moderator of intervention effectiveness. However, this BCT was only identified in two studies. In sum, no clear evidence links specific BCTs to intervention effectiveness.

Overall, the heterogeneity of coaching approaches and theoretical basis utilised in the interventions, in addition to inconsistent and vague reporting of BCTs makes it challenging to identify the active intervention components. Most studies provided insufficient details about the intervention content and mechanisms, including the lack of curriculum and coaching protocol. Furthermore, none of the included studies explicitly reported the use of BCTs in interventions. Thus, it is difficult to link specific BCTs with the effectiveness or success of any included interventions. Considering that the BCT taxonomy (V1)

[25] was developed in order to facilitate the systematic application and reporting of BCTs in interventions, inconsistent reporting of BCTs remains a key issue across the behaviour change and intervention development literature [62]. Consequently, interpreting and replicating some of the included interventions cannot be easily achieved due to the imprecise description of the content provided. This could be one explanation for why there is still variation in the reported effectiveness of health coaching interventions, as well as the continued replication of ineffective interventions.

Although the majority of the interventions used motivational interviewing as the underpinning theory, several BCTs that directly link to MI techniques, such as engaging techniques, focusing techniques, and evoking techniques, were completely absent as the used theoretical framework appeared to be inadequately incorporated during the interventions' development stage [63]. These BCTs are: *verbal persuasion about capability, information about health consequences, pros and cons, comparative imagining of future outcomes, mental rehearsal of successful performance, salience of consequences, focus on past success, valued self-identity, and social comparison.*

In addition, health coaching mainly aims to enable a client to develop new personal skills, such as developing self-efficacy, self-monitoring, enhancing and valuing self-identity, self-belief, and problem-solving [17]. However, the number of potential BCTs has never or rarely been reported across interventions despite direct and strong associations with the theoretical basis of health coaching. Some examples of the relevant BCTs are *behavioural contract, commitment, monitoring of emotional consequences, anticipated regret, comparative imagining of future outcomes, identification of self as a role model, framing/reframing,* and *focus on past success*. These BCTs were rarely mentioned across many of the included studies despite their significance as core components of any health coaching intervention advocated by International Coaching Federation (2019) [64].

Finally, explicit and accurate use of BCTs and the appropriate selection of theories help to prevent frequent mistakes and incorrect replication of ineffective interventions [61]. To accurately assess an intervention's efficacy and increase the likelihood that it will be successfully replicated, intervention developers need first to identify the intervention's active components and whether they directly link to improvement in the outcomes. BCTs need to be explicitly specified and included in the development of new interventions as it is highly recommended to precisely guide the intervention's procedures into effective interaction to bring about the desired behaviour change. Future studies are needed to identify the most effective BCTs to be used with health coaching interventions.

Strengths and limitations of this review

This review has various strengths. First, it is the first review to identify the use of BCTs in health coaching studies with T2DM. Second, this review conducted a meta-analysis to investigate and evaluate the effectiveness of the BCTs in health coaching interventions and whether there is a link between using specific BCTs and reductions in Hb1Ac. Third, using the BCTs taxonomy assisted in systematically investigating and analysing interventions' descriptions to identify the active ingredients of each intervention.

Additionally, there are several limitations to this review as well, which should be mentioned. First, it was limited to only English language papers, hence there is a possibility that some health coaching RCTs were not included. Second, studies have used various BCTs with different outcome measures, so it was difficult to determine which BCT assigned to HbA1c as an outcome. Consequently, it was difficult to be assured whether the positive results were achieved by individual BCTs or due to combinations of different BCTs. Inadequate reporting of intervention details and imprecise descriptions could lead to incorrect assumptions about the presence or absence of BCTs. Clarity and the amount of provided details on the interventions play a crucial role in coding BCTs correctly and so may have limited the accuracy of coding in the current review.

Conclusion

This systematic review and meat-analysis examined the available evidence to determine which BCTs may be linked to improving diabetic self-management by reducing the glycaemic index. The analysis of this review showed that only 3 of the 20 interventions reported medium-sized effects on HbA1c reduction. Overall, the health coaching interventions were found to have small but significant effect on reductions in HbA1c. Whilst our findings provide some evidence to support the use of health coaching as a strategy for eliciting positive impacts on behaviours and diabetes elf-management, it may not have fulfilled its potential. Until the BCTs included in interventions are accurately reported it will be difficult to isolate the key active ingredients of health coaching interventions. Therefore, it was challenging to draw a definitive conclusion, and more research is needed to determine which BCTs are most likely to help people with T2DM control their condition. For effective and replicable health coaching interventions to be developed, the precise use and reporting of theories and BCTs is needed.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12889-022-14874-3.

Additional file 1. Supplementary Material 1 Medline search strategy.

Additional file 2. Supplementary Material 2 Health Coaching Studies.

Acknowledgements
We would like to thank the University of Sheffield Institutional Open Access Fund for its support. This paper will be published under a Creative Commons Attribution (CC BY) licence.

Authors' contributions
ANA conceived of the idea and wrote the main manuscript text. ANA extracted the data from papers, and PN double-checked the data extraction. ANA and HH coded the intervention content to identify Behaviour Change Technique (BCT), and PN reviewed and helped to reach an agreement on coded BCTs. OC conducted the meta-analysis and PN reviewed it. PN, EG and SJC reviewed and critiqued the manuscript. All authors have read and approved the manuscript.

Funding
This research received no external funding

Availability of data and materials
All data generated or analysed during this study are included in this published article.

Declarations

Ethics approval and consent to participate
Not applicable.

Consent for publication
Not applicable.

Competing interests
The other authors have no conflicts of interest.

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Received: 16 August 2022 Accepted: 15 December 2022
Published online: 13 January 2023

References

1. Khan MAB, Hashim MJ, King JK, Govender RD, Mustafa H, Kaabi JA. Epidemiology of Type 2 Diabetes – Global Burden of Disease and Forecasted Trends. J Epidemiol Glob Health. 2020;10(1):107.
2. Centers for Disease Control and Prevention. Type 2 diabetes. 2021. https://www.cdc.gov/diabetes/basics/type2.html. Accessed 4 Apr 2022.
3. Global Report on Diabetes WHO Library Cataloguing-in-Publication Data Global report on diabetes; 2016.
4. Galaviz KI, Narayan KMV, Lobelo F, Weber MB. Lifestyle and the Prevention of Type 2 Diabetes: A Status Report. Am J Lifestyle Med. 2018;12(1):4–20.
5. Liu J, Ren Z-H, Qiang H, Wu J, Shen M, Zhang L, et al. Trends in the incidence of diabetes mellitus: results from the Global Burden of Disease Study 2017 and implications for diabetes mellitus prevention. BMC Public Health. 2020;20(1):1415.
6. Wroth SW. Health Coaching Bridges Gaps in Patient Care. Alternative and Complementary Therapies. 2015;21(4):157–9.
7. Aikaterini T, Papazafiropoulou AK, Melidonis A. Type 2 diabetes and quality of life. World J Diabetes. 2017;8(4):120.
8. Powell CK, Hill EG, Clancy DE. The relationship between health literacy and diabetes knowledge and readiness to take health actions. Diabetes Educ. 2007;33(1):144–51.
9. Lund SH, Aspelund T, Kirby P, Russell G, Einarsson S, Palsson O, et al. Individualised risk assessment for diabetic retinopathy and optimisation of screening intervals: A scientific approach to reducing healthcare costs. Br J Ophthalmol. 2016;100(5):683–7.
10. Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin; 2002.
11. Lindstrom J. Sustained reduction in the incidence of type 2 diabetes by lifestyle intervention: follow-up of the Finnish Diabetes Prevention Study. Lancet. 2006;368:1673–9.
12. Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. JAMA. 2002;288(19):2469–75.
13. Funnell MM, Anderson RM. Patient empowerment: a look back, a look ahead. The Diabetes Educator. 2003;29(3):454–64.
14. Holman H, Lorig K. Patients as partners in managing chronic disease : Partnership is a prerequisite for effective and efficient health care. BMJ : Brit Med J. 2000;320(7234):526.
15. Wong-Rieger D, Rieger FP. Health coaching in diabetes: empowering patients to self-manage. Can. J. Diabetes. 2013;37:41–4.
16. Temmingh H, Claassen A, Van Zyl S, Carrara H, Dayakalashe NM, Myer L, et al. The evaluation of a telephonic wellness coaching intervention for weight reduction and wellness improvement in a community-based cohort of persons with serious mental illness. J Nerv Ment Dis. 2013;201(11):977–86.
17. Wolever RQ, Simmons LA, Sforzo GA, Dill D, Kaye M, Bechard EM, et al. A Systematic Review of the Literature on Health and Wellness Coaching: Defining a Key Behavioral Intervention in Healthcare. Global Advances in Health and Medicine. 2013;2(4):38–57.
18. Butterworth SW, Linden A, McClay W. Health coaching as an intervention in health management programs. Disease Management & Health Outcomes. 2007;15:299–307.
19. Pirbaglou M, Katz J, Motamed M, Pludwinski S, Walker K, Ritvo P. Personal Health Coaching as a Type 2 Diabetes Mellitus Self-Management Strategy: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Am J Health Promot. 2018;32:1613–26.
20. Hill B, Richardson B, Skouteris H. Do we know how to design effective health coaching interventions: A systematic review of the state of the literature. Am J Health Promot. 2015;29(5):e158–68.
21. Alamri F, Radwan N, Elolemy A, Alkhashan H. Effectiveness of health coaching on diabetic patients: A Systematic Review and Meta-analysis. Tradit Med Res. 2019;4:314–25.
22. Davies MJ, Heller S, Skinner TC, Campbell MJ, Carey ME, Cradock S, et al. Effectiveness of the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: cluster randomised controlled trial. BMJ. 2008;336(7642):491–5.
23. van Bokhoven MA. Designing a quality improvement intervention: a systematic approach. Quality and Safety in Health Care. 2003;12:215–20.
24. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. Implement Sci. 2011;6(1):42.
25. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The Behavior Change Technique Taxonomy (v1) of 93 Hierarchically Clustered Techniques: Building an International Consensus for the Reporting of Behavior Change Interventions. Change Interventions Oral Medicine. 2013;46:81–95.
26. Avery L, Flynn D, Van Wersch A, Sniehotta FF, Trenell MI. Changing physical activity behavior in type 2 diabetes: a systematic review and meta-analysis of behavioral interventions. Diabetes Care. 2012;35(12):2681–9.
27. Cradock KA, ÓLaighin G, Finucane FM, Gainforth HL, Quinlan LR, Ginis KAM. Behaviour change techniques targeting both diet and physical activity in type 2 diabetes: A systematic review and meta-analysis. Int. J. Behav. Nutr. Phys. Act. 2017;14:18.

28. Hankonen N, Sutton S, Prevost AT, Simmons RK, Griffin SJ, Kinmonth AL, et al. Which behavior change techniques are associated with changes in physical activity, diet and body mass index in people with recently diagnosed diabetes? Ann Behav Med. 2015;49(1):7–17.
29. Van Vugt M, De Wit M, Cleijne WHJJ, Snoek FJ. Use of behavioral change techniques in web-based self-management programs for type 2 diabetes patients: systematic review. J Med Internet Res. 2013;15(12):e279.
30. Presseau J, Ivers NM, Newham JJ, Knittle K, Danko KJ, Grimshaw JM. Using a behaviour change techniques taxonomy to identify active ingredients within trials of implementation interventions for diabetes care. Implement Sci. 2015;10(1):1–10.
31. Upsher R, Onabajo D, Stahl D, Ismail K, Winkley K. The Effectiveness of Behavior Change Techniques Underpinning Psychological Interventions to Improve Glycemic Levels for Adults With Type 2 Diabetes: A Meta-Analysis. Frontiers in Clinical Diabetes and Healthcare. 2021;2:699038.
32. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JP, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. Br Med J. 2009;2700:112.
33. Bothwell LE, Greene JA, Podolsky SH, Jones DS, Malina D. Assessing the gold standard - Lessons from the history of RCTs. N Engl J Med. 2016;374(22):2175–81.
34. Frosch DL. Evaluation of a behavior support intervention for patients with poorly controlled diabetes. Arch Intern Med. 2011;171(22):2011–7.
35. Glasgow RE, Nutting PA, Toobert DJ, King DK, Strycker LA, Jex M, et al. Effects of a brief computer-assisted diabetes self-management intervention on dietary, biological and quality-of-life outcomes. Chronic Illn. 2006;2(1):27–38.
36. Kim MT, Kim KB, Huh B, Nguyen T, Han H-R, Bone LR, et al. The effect of a community-based self-help intervention. Am J Prev Med. 2015;49(5):726–37.
37. McKay HG, Glasgow RE, Feil EG, Boles SM, Barrera M Jr. Internet-based diabetes self-management and support: initial outcomes from the diabetes network project. Rehabil Psychol. 2002;47(1):31–48.
38. Ruggiero L, Moadsiri A, Butler P, Oros SM, Berbaum ML, Whitman S, et al. Supporting diabetes self-care in underserved populations. Diabetes Educ. 2010;36(1):127–31.
39. Sacco WP, Malone JI, Morrison AD, Friedman A, Wells K. Effect of a brief, regular telephone intervention by paraprofessionals for type 2 diabetes. J Behav Med. 2009;32(4):349–59.
40. Thom DH, Ghorob A, Hessler D, De Vore D, Chen E, Bodenheimer TA. Impact of peer health coaching on glycemic control in low-income patients with diabetes: a randomized controlled trial. Ann Fam Med. 2013;11(2):137–44.
41. Whittemore R, Melkus GDE, Sullivan A, Grey M. A nurse-coaching intervention for women with type 2 diabetes. Diabetes Educ. 2004;30(5):795–804.
42. Willard-Grace R, Chen EH, Hessler D, DeVore D, Prado C, Bodenheimer T, et al. Health coaching by medical assistants to improve control of diabetes, hypertension, and hyperlipidemia in low-income patients: a randomized controlled trial. Ann Fam Med. 2015;13(2):130–8.
43. Wolever RQ, Dreusicke M, Fikkan J, Hawkins TV, Yeung S, Wakefield J, et al. Integrative health coaching for patients with type 2 diabetes. Diabetes Educ. 2010;36(4):629–39.
44. Chen J-H, Ou H-T, Lin T-C, Lai EC-C, Yang Kao Y-H. Pharmaceutical care of elderly patients with poorly controlled type 2 diabetes mellitus: a randomized controlled trial. Int J Clin Pharm. 2016;38(1):88–95.
45. Lin CL, Huang LC, Chang YT, Chen RY, Yang SH. Effectiveness of health coaching in diabetes control and lifestyle improvement: a randomized-controlled trial. Nutrients. 2021;13(11):3878.
46. Basak Cinar A, Schou L. Health promotion for patients with diabetes: health coaching or formal health education? Int Dent J. 2014;64(1):20–8.
47. Sherifali D, Brozic A, Agema P, Punthakee Z, McInnes N, O'Reilly D, et al. Effect of Diabetes Health Coaching on Glycemic Control and Quality of Life in Adults Living With Type 2 Diabetes: A Community-Based, Randomized. Can J Diabetes. 2021;45(7):594–600.
48. Cho J-H, Kwon H-S, Kim H-S, Oh J-A, Yoon K-H. Effects on diabetes management of a health-care provider mediated, remote coaching system via a PDA-type glucometer and the internet. J Telemed Telecare. 2011;17(7):365–70.
49. Holmen H, Torbjørnsen A, Wahl AK, Jenum AK, Småstuen MC. A Mobile Health Intervention for Self-Management and Lifestyle Change for Persons With Type. JMIR mHealth and uHealth. 2014;2:4–4.
50. Karhula T, Vuorinen A-L, Rääpysjärvi K, Pakanen M, Itkonen P, Tepponen M, et al. Telemonitoring and mobile phone-based health coaching among Finnish diabetic and heart disease patients: randomized controlled trial. J Med Internet Res. 2015;17(6):e153.
51. Kempf K, Altpeter B, Berger J, Reuß O, Fuchs M, Schneider M, et al. Efficacy of the telemedical lifestyle intervention program TeLiPro in advanced stages of type 2 diabetes: a randomized controlled trial. Diabetes Care. 2017;40(7):863–71.
52. Odnoletkova I, Goderis G, Nobels F, Fieuws S, Aertgeerts B, Annemans L, et al. Optimizing diabetes control in people with Type 2 diabetes through nurse-led telecoaching. Diabet Med. 2016;33(6):777–85.
53. Varney JE, Weiland TJ, Inder WJ, Jelinek GA. Effect of hospital-based telephone coaching on glycaemic control and adherence to management guidelines in type 2 diabetes, a randomised controlled trial. Intern Med J. 2014;44(9):12515.
54. Cohen J. Statistical power analysis for the behavioral sciences. 2nd ed. New York: Lawrence Erlbaum Associates Inc.; 1988.
55. Morris SB. Estimating effect sizes from pretest-posttest-control group designs. Organ Res Methods. 2008;11(2):364–86.
56. Suurmond R, van Rhee H, Hak T. Introduction, comparison, and validation of Meta-Essentials: a free and simple tool for meta-analysis. Res Synth Methods. 2017;8(4):537–53.
57. Higgins JPT, Altman DG, Gotzsche PC, Juni P, Moher D, Oxman AD, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ. 2011;343(2).
58. Lameijer A, Fokkert M, Edens M, Slingerland R, Bilo H, van Dijk P. Determinants of HbA1c reduction with FreeStyle Libre flash glucose monitoring (FLARE-NL 5). J. Clin. Transl. Endocrinol. 2020;22:100237.
59. Olsen JM, Nesbitt BJ. Health Coaching to Improve Healthy Lifestyle Behaviors: An Integrative Review. Am J Health Promot. 2010;25(1):e1–e12.
60. Michie S, Abraham C, Whittington C, McAteer J, Gupta S. Effective techniques in healthy eating and physical activity interventions: a meta-regression. Health Psychol. 2009;28(6):690.
61. Prestwich A, Sniehotta FF, Whittington C, Dombrowski SU, Rogers L, Michie S. Does theory influence the effectiveness of health behavior interventions? Meta-analysis. Health Psychol. 2014;33(5):465.
62. Michie S, Johnston M. Theories and techniques of behaviour change: Developing a cumulative science of behaviour change. Health Psychol Rev. 2012;6:1–6.
63. Hardcastle SJ, Fortier M, Blake N, Hagger MS. Identifying content-based and relational techniques to change behaviour in motivational interviewing. Health Psychol Rev. 2017;11(1):1–16.
64. International Coaching Federation. ICF core competencies. 2022. https://coachingfederation.org/credentialsand-standards/core-competencies. Accessed 10 Apr 2022.

Publisher's Note

Supplementary Material 1: Medline search strategy:

Search Strategy:

#	Searches	Results
1	randomized controlled trial.mp. or Randomized Controlled Trial/	606309
2	randomised controlled trial.mp.	28608
3	clinical trial.mp. or Clinical Trial/	766552
4	1 or 2 or 3	1080933
5	Health coaching.mp.	830
6	Coaching.mp.	8384
7	coach*.mp.	18612
8	health counselling.mp.	236
9	health coach*.mp.	1117
10	personal coach*.mp.	69
11	Health Promotion/ or personal coaching.mp.	79481
12	5 or 6 or 7 or 8 or 9 or 10 or 11	97599
13	type II diabetes mellitus.mp.	3177
14	non-insulin dependent diabetes mellitus.mp.	6900
15	Diabetes Mellitus, Type 2/ or diabetes mellitus, type 2 diabetes mellitus.mp.	157749
16	13 or 14 or 15	160593
17	4 and 12 and 16	405
18	limit 17 to (english language and humans and yr="1950-current" and "all adult (19 plus years)")	326

Published paper ended

Chapter Summary

This study has successfully fulfilled the first objective of the research. The findings of this study are essential to inform the implementation process of the planned feasibility study. One of the critical findings of this review was that the intervention descriptions of many studies were poorly reported, providing imprecise information that would hinder successful replication in the future. As a result, undertaking a feasibility study would be more significant to explore and assess the trial and guide the decision on proceeding to a larger RCT. Moreover, it is noteworthy that none of the studies encompassed in the analysis explicitly reported the inclusion or implementation of BCTs. This demonstrates the importance of collecting and explicitly reporting adequate information about the intervention to allow for effective evaluation of its content and appropriate interpretation of the study results, in this case, to inform a potential future definitive trial. All the feasibility study information, including the intervention curriculum, is presented in detail in the next chapter.

CHAPTER 4: METHODS

4.1 Introduction

The systematic review (see Chapter 3) discussed the nature of the problem and identified some related limitations with health coaching content, including imprecise descriptions and insufficient details. This chapter aims to address this gap through the COM-B model and TDF framework. This chapter links the identified barriers and target behaviours (see Chapter 2) to specific intervention functions and BCTs to provide a clear roadmap to carry out health coaching activities as planned.

The first section of this chapter discusses the importance of conducting a feasibility study to guide the development of future definitive trials. It also provides an overview of the research methodology, the philosophy used in the study, and the rationale for the selected research approach. The second section of this chapter discusses the research design, including methods used, data collection instrument, analysis plan, ethical approval, proposed timetable, risk assessment, and value of this research, which has been peer-reviewed and published[129]. Furthermore, additional details beyond what is outlined in the protocol paper are provided in this section at the end of this chapter. The study's ethical approval and participation consent form are presented in Appendix 13. The study methods are outlined according to CONSORT guidance, including the trial design, participants, recruitment strategy, outcome measures, sample size, and intervention content.

4.2 Section I

4.2.1 The rationale for conducting a feasibility study before a definitive trial of health coaching in SA

Based on the systematic review findings (see Chapter 3), it became clear that significant gaps and discrepancies in the results of the studies and how they were developed exist. Looking at the results of the studies, it became evident that there was no agreement on methods for carrying out health coaching interventions or on recommendations for replication. One of the biggest limitations found across most of the studies included in the review was the lack of clarity in the description, especially the 'active ingredients' used in most interventions. This made it more difficult to understand, interpret, and replicate the interventions, especially in a different context. Understanding the 'active ingredients' used in an intervention content is crucial in effectively replicating an intervention[130].

It is recommended to perform a thorough feasibility analysis prior to embarking on a comprehensive trial, particularly when introducing a new intervention into an unfamiliar context. This will enable the identification of potential uncertainties and facilitate their explanation in a timely and effective manner [125]. Many examples demonstrate the cultural context's role in the success or failure of new applied programmes or interventions. For instance, "a feasibility study for an evaluation of an adolescent sexual health intervention in rural Zimbabwe found that the planned classroom-based programme was inappropriate, given the cultural norms, teaching styles, and relationships between teachers and pupils in this country, and it was replaced by a community-based programme" [125]. This example illustrates the value of exploring the feasibility and the significance of considering the intervention context to avoid any potential undesired results.

Saudi society has a unique culture and shared norms – as previously discussed (see Chapter 2) – which require close attention and consideration, especially when implementing new interventions. As Booth et al. (2019) state, when making decisions about complex interventions, developers must take into account the sociocultural acceptability of the proposed intervention and how feasible the intervention will be[131]. In Middle Eastern countries, specifically SA, often it is unacceptable to simply implement interventions which have been developed in Western countries (e.g., Europe or the US) without adaptation. An adapted intervention is vital, more viable, and cost-effective when there is a lack of evidence-based interventions that have been developed and assessed for the target population [132].

Conducting feasibility studies is helpful in evaluating the suitability of procedures, including the recruitment and retention process, as well as determining the appropriate sample size for a full-scale trial [125]. These studies help identify potential issues, including study protocol, practicality, context-specific relevance, and the possibility of efficacy [133]. One of the distinctive features of conducting the feasibility study is that it helps this research explore and integrate stakeholders' experiences during the implementation phase to fulfil the most desirable format rather than waiting until the end of study [134].

Involving relevant stakeholders during a feasibility study is a significant step that deepens researchers' knowledge about the intervention context. The rationale for engaging stakeholders is that they help prioritise, identify, and understand the real problem and help find practical and realistic solutions that make a difference in future large trials in the real world [135]. Co-production with stakeholders leads the intervention providers to a better understanding of the context and conditions in which it would operate. Co-production is crucial to building the trust needed with stakeholders to facilitate the acceptability and engagement with the intervention. The involvement of stakeholders could be through workshops, meetings, and/or interviews to

construct a partnership to facilitate a comprehensive understanding of the issue and generate new ideas [135].

Before I started the study, I conducted several meetings and interviews with relevant stakeholders, including healthcare providers and patients with T2DM, to gain their perspectives. The first face-to-face meeting included five doctors, a dietician, and four health educators and served as an introductory session to outline the study's objectives and discuss potential collaboration. Further meetings were more focused on understanding the real-world challenges and settings of managing T2DM in SA. During these discussions, we tackled barriers preventing patients from adopting healthier behaviours and examined ways to make the study's goals more applicable to the Saudi context. For example, we considered social norms and the stigma associated with T2DM, which were later integrated into the intervention design. Additionally, I interviewed two patients with T2DM to gain insights into their perceptions of current healthcare practices and how a more personalised intervention might be more effective.

While it is important to note that health coaching has shown some effectiveness in Saudi primary care settings for weight loss [22], it remains crucial to consider that interventions successful in Western societies may not automatically translate to other conditions or cultural contexts like SA. As a result, it is essential to adapt these interventions to make them more practical, culturally acceptable, and suitable for the unique social and cultural aspects of Saudi society. Craig et al. (2018) stated, "A careful investigation of contextual factors is equally important when interventions developed and tested in one context are being adapted for use elsewhere"[136]. Consequently, underestimation of the significance of context may lead to difficulties with implementation, which could negatively impact effectiveness, even if an intervention showed a positive outcome in another context[136].

To the best of the researcher's knowledge, no previous health coaching programmes have utilised the COM-B model to construct intervention content and analyse intended outcomes systematically. Furthermore, there is a limited number of diabetes self-management studies within the Saudi context, with a predominant focus on providing health education rather than comprehensive interventions [65]. Additionally, none of the self-management interventions have actively engaged stakeholders in the development process, potentially leading to a failure to address the challenges patients face in managing their diabetes [65]. Consequently, this feasibility study is aimed to evaluate the practicality and acceptability of the adapted health coaching intervention tailored explicitly for Saudi patients with T2DM, ensuring its alignment with the local health system and the cultural context.

4.2.2: Research philosophy

The primary focus of research philosophy, according to Saunders et al. (2009), is the development and nature of knowledge[137]. The way researchers perceive reality significantly shapes their comprehension, as well as how hypotheses are created, and research is planned and carried out. In the context of the research field, several research philosophies, including axiology, epistemology, and ontology to be highlighted for their significant contribution to researchers' understanding of the study's structure or paradigm. Given that not all studies need to follow the same methodology, selecting a study's structure or paradigm depends on evaluating the study's objectives and goals to determine the most appropriate approach[138].

Due to the implications of the researchers' worldviews and perceptions toward research constructs, including the ontology (reality and truth), how they comprehend it (epistemology), and methods of attaining it (methodologies), it is crucial to highlight the philosophical assumptions and research paradigm at the beginning [139]. The researchers' view of ontology lies under either objectivism or subjectivism and under three epistemological positions; positivism,

interpretivism, and realism [137]. The fundamental difference between the two philosophical forms, objectivism, and subjectivism, lies in the research assumptions about the nature of reality and how it can be obtained.

Objectivism means that reality is viewed independently, separated from the social structures and actors. Positivism, usually aligned with objectivism, is used in evaluating and explaining existing theories [138], in which positivists believe that the nature of reality is a single truth that can be, determined and assessed by the deductive reasoning process, often by quantitative methods [139]. Conversely, subjectivism views social phenomena, events, and actions as the main subjective cornerstone[138]. Constructivists, within the subjectivism form, believe that knowledge and underlying meaning need to be explored from multiple realities by the inductive reasoning process, often by qualitative method[139].

In the context of this study, both objectivism and subjectivism were utilised. Objectivism was used to view and interpret statistical realities, including questionnaires and preliminary outcomes (quantitative part), while subjectivism was used when exploring the study's acceptability through health coaches' and participants' views and perceptions (qualitative part). A pragmatic worldview combines positivism and interpretivism to assist in understanding research activity[138]. A mixed methods design was selected to combine quantitative and qualitative parts to carry out the research objectives and provide rich and comprehensive knowledge. Therefore, pragmatism was selected as the most appropriate epistemological paradigm for mixed methods studies [140].

4.2.3 Research approaches:

This study used a mixed methods design, including the two main research approaches, quantitative and qualitative. Quantitative approaches are described as associated with the

computation of numeric data and using statistical techniques to evaluate information in order to identify relationships between research variables[138]. Qualitative studies, on the other hand, seek to investigate people's experiences and perceptions primarily collected from focus groups and interviews [140].

4.2.4 The rationale for selecting mixed methods design:

This study was grounded on a pragmatic worldview because the combination of qualitative and quantitative methodologies is more likely to address research objectives better and provide a comprehensive understanding of the study inquiries[141]. In addition, this design helped in exploring reality not only from a single method but from two different methods, using more textual and statistical data to efficiently respond to the study's problems [141]. In the context of the feasibility study, we sought to maximise this opportunity to provide a complete understanding of the potential of conducting a large-scale intervention by incorporating both qualitative and quantitative methods in a single study, which was impossible if only one method was used. Therefore, one of the six mixed methods design approaches should be considered when combining qualitative and quantitative data[140].

4.2.5 Research design:

The convergent design was selected to combine quantitative and qualitative methods to better understand the research inquiries[142]. Given that this study's quantitative and qualitative data were collected and analysed concurrently, the convergent design was the most appropriate design to use[140]. The design allowed for further exploration of the feasibility, usability, and acceptability of the health coaching intervention among adults diagnosed with T2DM in SA. A joint display of data was used for interpretation by merging and integrating the two forms of data[140].

4.2.6 Research quality:

To assess the rigours of qualitative data, the trustworthiness should be examined through different factors, including credibility, transferability, objectivity and confirmability (Lincoln & Guba 1985; Anney, 2014)[143] [144]. Pilot & Beck (2012) define *trustworthiness* as the level of confidence in the collected data, its interpretation, and the methods used to assess the quality of the research[145]. Hence, the trustworthiness of a research method can be used to evaluate the value of its findings[143]. The quantitative methods, on the other hand, required the validity and reliability of the research procedures to fulfil the quality of the study's outcomes [146]. By employing validated measures and avoiding selection bias through random selection, the study adhered to the requirements of validity and reliability in its processes. As this was a feasibility study, it was more concerned with informing the decision and design of a larger definitive trial than it was to ensure the generalizability of the results, given the nature of the research, its context and the sample size [147]. Nonetheless, recruiting procedure, sampling randomisation, data collection and data analysis procedure, and context of the feasibility study were described in further detail under the methods section in this chapter.

4.3 Section II

This section provides the research methodology to explore the feasibility and acceptance of a health coaching intervention for T2DM patients in SA through a mixed methods feasibility RCT. The chapter has undergone peer-review and is now published in the International Journal of Environmental Research and Public Health. It falls under a Creative Commons Attribution (CC-BY) license, providing us unrestricted usage of the final published PDF. The ensuing pages preserve the layout from the final publication.

4.3.1 Publication reference

Almulhim, A.N.; Goyder, E.; Caton, S.J. Assessing the Feasibility and Acceptability of Health Coaching as a New Diabetes Management Approach for the People with Type 2 Diabetes in SA: A Protocol for a Mixed Methods Feasibility Study. Int. J. Environ. Res. Public Health 2022, 19, 15089. https://doi.org/10.3390/ijerph192215089

4.3.2 Authors Contributions

The authors' contributions to this paper are as follows: Abdullah Almulhim played the leading role in conceptualizing, developing the methodology and software, validating, allocating resources, curating data, preparing the original draft, and reviewing and editing the manuscript. Abdullah Almulhim was responsible for applying for research funding (publication fee). Elizabeth Goyder and Samantha Caton provided supervision and participated in the writing, review, and editing process. All authors have carefully read and approved the final version of the published manuscript. The following pages maintain the layout of the final publication

International Journal of
Environmental Research and Public Health

MDPI

Protocol

Assessing the Feasibility and Acceptability of Health Coaching as a New Diabetes Management Approach for the People with Type 2 Diabetes in Saudi Arabia: A Protocol for a Mixed Methods Feasibility Study

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Abstract: Background: Over recent years, the Middle East, and especially Saudi Arabia, has faced multiple changes, including structural-demographic and economic shifts. This has led to massive changes in the population's lifestyle, including more unhealthy diets and increases in physical inactivity. As a result, accelerating rates of chronic diseases, including type 2 diabetes mellitus (T2DM) are a major public health concern. Current diabetes care in Saudi Arabia focuses on increasing the awareness of patients through various approaches, mainly based on health education, which is found to be suboptimal and ineffective for improving long-term outcomes. This study aims to assess the feasibility and acceptability of using a client-centred approach called health coaching that supports, enables, and engages T2DM patients to take the central role of controlling their own conditions by developing new crucial skills. Methods: A mixed methods randomised controlled feasibility study of health coaching will be used. Participants (n = 30) are adults with T2DM with poorly controlled diabetes (A1C $\geq$ 7) who can read and write in Arabic. Eligible participants are randomly allocated to either an intervention or control group for 12 weeks. COM-B model and Behaviour Change Technique Taxonomy version 1 (BCTTv1) guide the intervention curriculum. Predetermined progression criteria will be used to determine whether to proceed to a larger trial or not. Outcomes will be measured at baseline and 3 months. The study's primary aim is to assess the process of eligibility, recruitment, retention and completion rates, acceptability and suitability of intervention and the time to complete each procedure. The preliminary efficacy of health coaching is the secondary outcome that includes different measurements, such as HbA1c, blood pressure, body mass index (BMI), waist circumference, weight, patients' self-efficacy, and diabetes self-management. Discussion: This is the first study to explore the feasibility, acceptability, and preliminary efficacy of health coaching that used the Capability, Opportunity, Motivation, Behaviour (COM-B) model and BCTTv1 as guidance to develop the intervention for adults with T2DM in Saudi Arabia. The findings of this study will be used to inform the larger RCT trial if it is shown to be feasible and acceptable.

Keywords: health behaviour change; health coaching; self-management; behaviour change techniques; type 2 diabetes

Citation: Almulhim, A.N.; Goyder, E.; Caton, S.J. Assessing the Feasibility and Acceptability of Health Coaching as a New Diabetes Management Approach for the People with Type 2 Diabetes in Saudi Arabia: A Protocol for a Mixed Methods Feasibility Study. *Int. J. Environ. Res. Public Health* **2022**, *19*, 15089. https://doi.org/10.3390/ijerph192215089

Academic Editor: Emanuela Orsi

Received: 4 October 2022
Accepted: 11 November 2022
Published: 16 November 2022

1. Background

Type 2 diabetes mellitus (T2DM) is a widespread chronic disease that poses a real worldwide health threat that is becoming a significant public health concern. T2DM is profoundly impacted by an excess body mass index (BMI) and physical inactivity [1]. Diabetes contributes to lead patients developing severe complications such as heart and stroke disorders, eye problems and complications with hearing, kidney failure, nerve injury, amputations, oral issues, and foot problem [2]. Adults with diabetes are two or three

times more likely to develop heart problems and strokes [3]. In addition, there are other negative impacts of diabetes on social life, economic status, and health care services. Since diabetes is a preventable disease, which is strongly related to and affected by lifestyle, self-management is an optimal way to effectively manage it [4].

Worldwide, and especially in Saudi Arabia (SA), the prevalence of T2DM is growing at an alarming pace. According to a WHO report (2017), SA has the second highest rate of T2DM and is ranked the seventh highest in the globe. Additionally, the prevalence rate of T2DM has increased tenfold in the past three decades in SA. About 89% to 97% of all Saudi patients with diabetes are diagnosed with T2DM [5]. About seven million people suffer from T2DM in Saudi Arabia and three million are pre-diabetic. T2DM affects approximately 30% of the Saudi population and this increases with age [6]. The prevalence of T2DM is higher among women than men and with higher BMI individuals [6]. Moreover, it is more than likely that the burden of this chronic disease will only increase owing to factors such as an increased rate of obesity, an ageing population, changing lifestyles and poor diet [7]. The widespread increase in sedentary behaviour and physical inactivity among Saudis contributed to increasing the prevalence of T2DM [8] In SA the high rate of T2DM is associated with the high prevalence of obesity as a result of the fast urbanisation that led to adopting modern western dietary habits such as fast-food and increasing the level of physical inactivity [9].

The healthcare system in SA is still trying to address the alarming challenge of T2DM through several national programs and initiatives, but the outcome is still suboptimal. In SA, several studies have provided evidence that T2DM is not managed effectively [10]. While the current attempts are heavily reliant on awareness-raising campaigns, T2DM patients are still struggling to adopt a healthy diet and lifestyle to manage their conditions effectively. Adopting a healthy diet and lifestyle is an essential element of effective self-management of diabetes [11]. It is noteworthy that lifestyle interventions seem to be at least as effective as medications [12].

Diabetes education-based programs have not always been entirely adequate in bringing about the desired change. Many studies make it clear that awareness alone does not contribute to better self-management practices [13]. The responsibility of controlling T2DM is largely dependent on individual behaviour. T2DM patients are the key players to address this issue, so they need enough time to address their needs to improve their self-management skills. Healthcare providers often do not have adequate time for a face-to-face discussion with patients since regular visits at primary care clinics are usually restricted to 10 to 15 min, which leads to patients feeling negative, overwhelmed, and frustrated. Cost-effective interventions are needed to bridge the gap by listening to patients and helping them to overcome potential barriers. Developing a patient's self-management skills is crucial to delay or reducing the risk of T2DM. The occurrence of the chronic conditions associated with T2DM can be remarkably diminished or delayed—by 75% or more—with the help of healthier lifestyle behaviour choices made by patients [14]. Self-management interventions are needed that enable patients to control and manage T2DM [15] consistent with the current diabetes treatment philosophy that promotes patient-centred approaches [16].

There have been recent attempts to improve diabetes care in SA with T2DM through diabetes self-management programs. These programs are very uncommon and not gaining widespread adoption [17]. Most lifestyle interventions still rely on education as the core element to improve patients' self-care. The impact of diabetes education programs is suboptimal [17]. However, most studies have emphasised the significant need to shift the current attention toward employing new approaches that help patients to develop self-management skills. A recent systematic review, conducted on gulf cooperation council countries, included studies in T2DM self-management between 1996 and 2015 and found that none of the studies employed the skills needed to improve patients' self-management capability, such as problem-solving skills [5]. Moreover, none of the studies has employed a patient-centred approach to work with a patient as an ally rather than an educator. Client-

centred interventions that are tailored to the patient's needs are more likely to bring about desired outcomes [18].

Health coaching is a client-centred approach that is derived from different disciplines and behaviour change theories. It has become an emerging trend in the literature and is gaining widespread acceptance in the health promotion fields but this one-on-one type of tailored intervention has not yet been used in Saudi healthcare systems. Different studies have revealed that health coaching as an intervention centred on patients' values may provide added benefits to traditional T2DM education programmes [19]. It can be a highly effective and financially viable model when it focuses on improving patients' self-efficacy and important skills, including goal-setting, and problem-solving [20]. Health coaching has been applied in multiple different contexts and showed as an effective tool to improve diabetes self-management [21,22].

However, recent systemic reviews of randomised controlled trials utilising health coaching have reported mixed results, with some reporting that health coaching is effective, while others claim it is ineffective [21,22]. One of the explanations for the inconsistent reported findings across different studies is the lack of agreement on the active ingredients and content of effective health coaching interventions.

There is currently no consensus in the literature on designing an effective health coaching intervention, including the selection of a suitable theoretical basis and active ingredients, or behaviour change techniques [22]. In the absence of such consensus, there is uncertainty towards which coaching methods are more appropriate and effective to use including intervention content as well as the duration, length, and mode of delivery of sessions, particularly when applying health coaching in a new setting [23]. A lack of guidance, ineffective methods used to develop interventions, inappropriately selected intervention components and variation in the reporting of outcomes have been suggested to contribute to the mixed effectiveness of health coaching interventions [24–26]. Furthermore, health coaching interventions that have been developed and have succeeded in Western or other contexts may not be effective for people in different contexts such as SA. Consequently, such interventions may require adaptation and modification to make them more feasible, acceptable, and suitable in the context of Saudi society.

A feasibility study is highly recommended prior to a full-scale trial to test potential uncertainties, especially when a complex intervention is to be applied in a new context [27]. Feasibility studies help to explore specific issues such as study protocol, context-specific relevance, practicality, and the possibility of efficacy [27,28]. In addition, feasibility studies help examine the procedures' acceptability, assess the recruitment and retention process, and determine the appropriate sample size for a future full-scale trial [27].

To the best of our knowledge, none of the previous health coaching programs have used the BCW model and BCTs taxonomy as a guide to build the intervention content systematically in order to analyse and achieve planned outcomes. This is aside from the fact the application of diabetes self-management studies within the Saudi context is very uncommon and often focuses on providing health education [17]. Moreover, none of the self-management interventions have engaged stakeholders during the intervention development process, so the interventions may have failed to bring about the change and address the difficulties patients encounter in managing their diabetes [17].

As a result, the future full-scale intervention would be effectively refined and/or inactive ingredients replaced with other appropriate BCTs. Careful selection of theoretical framework and BCTs prior to the intervention being conducted is crucial and widely recommended [29].

1.1. Study Aims

The present feasibility study aims to determine whether the health coaching intervention for type 2 diabetes is feasible and acceptable to improve self-management and reduce HbA1C to inform a full-scale RCT trial in SA. The objectives of the study are categorised into the process evaluation objectives (primary) and outcome (secondary) objectives. The

process evaluation objectives are related to the implementation phase and mainly focus on the feasibility of processes and procedures of the study. The outcome objectives are related to the efficacy of the intervention.

1.1.1. Primary Objective: (Study Feasibility-Process Evaluation-Objectives)

To assess the feasibility of conducting a future definitive study to evaluate the effectiveness of using an adapted health coaching intervention in the Saudi context by:

1. Assessing recruitment, and retention rates, and estimating the effect size;
2. Assessing the implementation process, including data collection procedures;
3. Assessing and determining the sample size for the larger-scale trial using the findings of this feasibility study;
4. Exploring the acceptability and suitability of intervention through participants' perceptions of, and experiences with, the health coaching intervention.

1.1.2. Secondary Objective: (Outcome Objectives)

To assess the preliminary efficacy of health coaching to improve diabetes self-management and reduce HbA1C by evaluating its influence on participants' behaviours and their self-management ability compared to usual diabetes care by:

HbA1c and other variables will be assessed pre- and post-intervention at baseline and at 3 months. The intervention's clinical goal for T2DM self-management is an HbA1c level of <7.0%. Other variables will also be assessed; namely, glycosylated haemoglobin (HbA1C), blood pressure, body mass index (BMI), waist circumference, weight, patients' self-efficacy, and diabetes self-management.

2. Methods

The protocol of this study is following the guidance of CONSORT [30]. The methods are categorised into subsections presented below (see Supplementary File S1).

2.1. Study Location

Saudi Arabia will be the location of this study. The trial will only be conducted at one site, namely the obesity, endocrine, and metabolism centre at King Fahad Medical City (KFMC), the hub of the Riyadh Second Health Cluster. KFMC is one of Saudi Arabia's most significant and well-known medical cities, which serves the country's largest medical complex.

2.2. Trial Design

The present study will adopt a double-blind randomised two-arm feasibility trial to investigate the feasibility of a 3-month intervention for participants who have had difficulty managing their T2DM. Mixed methods will be employed in the study's design to gather and analyse both quantitative and qualitative data. A mixed methods approach allows the study to address additional research questions [31]. An RCT will be used since it is the best design for comparing the effectiveness of health coaching between the two groups [32]. The primary and secondary trial outcomes will be examined using various approaches, including questionnaires, interviews, focus groups, and clinical measures, to assess the intervention's feasibility, acceptability, and preliminary effects. The study evaluation will be conducted at two points: at the intervention's baseline and three months following the intervention (endpoint). To conduct this study, ethical approval was obtained by the University of Sheffield and the Institutional Review Board (IRB) committee form ethical approval at (KFMC) (IRB Log Number: 21-062E). The CONSORT flow diagram will describe the route participants take through the health coaching intervention, including the schedule of enrolment, interventions, and assessments [33].

2.3. Participants

The target population of this study is adult men with T2DM (HbA1c) ≥7.0%. Participants will be eligible for recruitment as per the following criteria:

2.4. Eligibility Criteria

- Aged >18 years old;
- The participant diagnosed with T2DM;
- Haemoglobin A1c (A1c) ≥7.0%;
- The participant can read and understand Arabic;
- The participant has access to a personal mobile phone/smartphone;
- The participant is willing to complete the intervention period;
- The participant is willing to remain in Riyadh.

Patients are not eligible if they: (1) had physical impairments that prevented them from participating in physical activity, (2) patients are unable to understand or unwilling to give their informed consent.

2.5. Recruitment

Recruitment will take place at a primary care centre at KFMC. Advertising for the intervention will use multiple methods, including posters, brushers, social media and through health care provider referrals. Interested individuals will be assessed for eligibility to participate in the intervention. Those who meet the eligibility criteria will be contacted to meet with the research team to briefly explain the study and answer any related questions. Interested individuals will be given a booklet that explained the study and its aims before signing the consent form. Participants will complete a short initial screening assessment, including demographic information and baseline-related laboratory reports.

2.6. Randomisation and Blinding

All recruited participants will be randomised on a 1:1 ratio into one of two groups. The randomisation process will be carried out by an independent person out of this study and used a computer to generate random numbers. To minimise selection bias, eligible participants will have an equal opportunity of being allocated to each group. The researchers will remain unaware of which group a participant had been assigned to before the baseline assessment. Participants will be informed which group they have been assigned to after the baseline assessment.

2.7. Sample Size

To the best of our knowledge, there was no previous health coaching RCT feasibility study in the field to use as a reference for the sample size. Thus, this study seeks to recruit at least 9% (n = 30) of the sample size required to carry out a full trial [34], with a minimum of 12 participants in each group [35]. Participants will be randomly allocated to either the coaching group (n = 15) or the control group (n = 15).

2.8. Intervention

2.8.1. Intervention Content (Intervention Group)

Health coaching in the context of T2DM can be characterised as a complex intervention due to the various direct and indirect interacting components that impact the intervention's outcomes. Health coaching, as a complex approach, has arisen from multiple different behaviour change theoretical bases. While complex intervention is not a straightforward study with direct clear causal and effects interaction, several crucial requirements and careful considerations are required when replicating it. This is aside from the fact that health coaching combines various disciplines such as psychology with numerous theories into one approach. Thus, we used the model and Theoretical Domains Framework (TDF) as guidance in adapting the intervention into a new context, namely Saudi Arabia.

The intervention is drawn on the COM-B model and TDF to provide a precise and systematic description of the health coaching content. COM-B model is the central part of the Behaviour Change Wheel (BCW) that helps in identifying the interactive process from; capability, opportunity, and motivation required to bring about the desired behaviours of an intervention [23]. The Theoretical Domains Framework (TDF) is a tool to provide further

comprehensive explanations that link the COM-B model for a better understanding of the needed changes and determining the target behaviour [36]. Several barriers have been identified based on a literature review of previous work and what needs to be changed to bring about the desired outcomes. In addition, different target behaviours have been identified that would lead to adopting a healthy diet and lifestyle as advocated by UK lifestyle guidelines [37]. To the best of our knowledge, there are no evidence-based guidelines in SA for T2DM to adopt a healthy diet and lifestyle. Therefore, the UK lifestyle guidelines will be used due to their relevance to the Saudi context [5,37]. The UK lifestyle guideline will be utilised to identify the possible behaviour targets. In order to specify target behaviours, a discussion will be conducted with health practitioners at the health centre (the intervention setting), including a dietician, to reach an agreement on the behaviours list. The discussion helps assess and prioritise the target behaviours according to their potential effects, and possibility to be measured and achieved [38].

The four proposed behaviour targets are [37]:

- Decrease carbohydrate intake for each meal;
- Use unsaturated fats as much as possible (avoid saturated fats);
- Do exercise for 30 min, five days in a week;
- Monitor waist circumference, maintain it below (80 cm for women and 94 cm for men).

Based on the results from COM-B and TDF behaviour analyses, different intervention functions will be identified and linked to the key barriers (see Table 1). Next, the intervention functions will be assessed for their suitability based on APEASE criteria; affordability, practicability, effectiveness/cost-effectiveness, acceptability, safety/side effects and equity, as recommended by the BCW guide [23].

As recommended by BCW guide, multiple BCTs could be used for each identified intervention function [23]. The BCW guide suggests the most common and less frequently used BCTs for each intervention function. Different possible BCTs were identified and included as a part of intervention functions to deliver certain coaching activities and address the key barriers. The BCW guide, previous literature review analysis, including recent systematic review results for the most effective BCTs associated with a clinically significant reduction in HbA1C were all used to help in selecting BCTs. Some BCTs were selected as per the competencies of health coaching as recommended by ICF and the intervention-underpinning theories. As advocated by [39], the BCTs have been selected and matched to the underpinning theories used in this study motivational interviewing (MI) and the transtheoretical model (TTM). The BCTs used that match the MI techniques are presented (see Supplementary File S2) [40]. In addition, other BCTs used in the health coaching intervention that match the TTM are presented (see Supplementary File S3) [41]. All the identified BCTs were assessed according to APEASE criteria to ensure the possibility of using them in the intervention context. Table 2 maps the BCTs selected and their link to the key barriers and intervention functions.

Table 1. The BCTs selected and its link to the key barriers and intervention functions.

COM-B		TDF	Barrier	Intervention Function	BCTs
Capability	Psychological	Knowledge	Poor T2DM knowledge affect self-control Poor nutrition knowledge (what the association between diabetes and diet, type of healthy food) Poor knowledge about PA (how to engage in PA, how much time spend on PA, PA intensity, PA types, underestimate the role of PA	Education	5.1 Information about health consequences
	Physical	Physical skills	Lack of energy to do PA Lack or limited skills of physical skills to do exercise	Enablement Training	Enablement: 6.1 Demonstration of the behaviour 1.5 Review behaviour goal (s) 1.7 Review outcome goal (s) 2.3 Self-monitoring of behaviour 12.1 Restructuring the physical environment 4.1 Instruction on how to perform a behaviour' 3.1 Social support (unspecified) Training: 8.1 Behavioural practice/rehearsal 8.3 Habit Formation 8.4 Habit reversal 8.7 Graded tasks 15.4 Self-talk 10.9 Self-reward 2.2 Feedback on behaviour 2.3 Self-monitoring of behaviour
Opportunity	Social	Social influences	Social norms and habits: overuse of high calories food intake; carbohydrates and fats, eating together (collectives), and social courtesy to eat unhealthy diet	Enablement	Enablement: 1.3 Goal setting (outcome) 1.1 Goal setting (behaviour) 3.1 Social support (unspecified) 1.4 Action planning 1.2 Problem-solving 2.3 Self-monitoring of behaviour 8.7 Graded tasks 5.5 Anticipated regret 12.1 Restructuring the physical environment 12.2 Restructuring the social environment

Table 1. *Cont.*

COM-B		TDF	Barrier	Intervention Function	BCTs
Motivation	Physical	Environmental context and resources	Lack of time Lack of resources (environmental, appropriate climate and financial ability) Lack of access to do activity Overuse of cars for transportations	Restriction Environmental restructuring Enablement Modelling	Enablement: 1.3 Goal setting (outcome) 1.1 Goal setting (Behaviour) 3.1 Social support (unspecified) 1.4 Action planning 1.2 Problem-solving 2.3 Self-monitoring of behaviour 9.2 Pros and cons 9.3 Comparative imagining of future outcomes 8.7 Graded tasks 1.9 Commitment 13.2 Framing/reframing 5.5 Anticipated regret 12.5 Adding objects to the environment Modelling: 6.1 Demonstration of the behaviour Environmental restructuring: 12.1 Restructuring the physical environment 7.1 Prompts/Cues Restriction: Use rules to reduce opportunity to engage in unwanted behaviour
	Reflective	Beliefs about own capability	Lack of willpower and self-confidence to do PA and maintain healthy diet	Persuasion Education Enablement	Persuasion: 15.1 Verbal persuasion about capability 15.2 Mental rehearsal of successful performance 9.1 Credible source 2.2 Feedback on behaviour 13.2 Framing/reframing 15.3 Focus on past success Education: 5.1 Information about health consequences 5.3 Information about social and environmental consequences Enablement: 1.9 Commitment 5.5 Anticipated regret
		Beliefsconsequences	Fear from consequences of PA (fear of injury and disease future complications)	Education	5.1 Information about health consequences
		Social role and identity	Struggle to change social identity associated with culture diet Struggle to accept the fact of living with diabetes	Education Persuasion	Education: 5.1 Information about health consequences Persuasion: 13.5 Identity associated with changed behaviour

Table 2. Health coaching intervention detailed protocol.

Phase #	Session Content	Session Goals	Intervention Function
1	• Session #1, the patient's assessment form and consent supposed to be completed • General introduction about the health coaching intervention • Outline the intervention structure and content • Discuss the coach's roles and the expectations from the participant (being completely clear with the client about the health coaching) • Creating an alliance (Establish Trust) • Learn from a patient (disease history, obstacles, priorities, strengths, goals, etc.) • Help patient to create wellness vision • Assess the readiness of patient's stage in relation to change health behaviour (the transtheoretical model) • Introduce the importance of having a healthy diet • Introduce the importance of increasing physical activity • Increase awareness of adopting a healthy lifestyle in relation to controlling diabetes • Identify 3-month general behavioural goals and biweekly goals • Explore resources needed to help achieve desirable behaviour • Commitment	• Identifying the patient's current position in the overall health status (via the transtheoretical model) • Build up a relationship (as an ally) between patient and coach • Encourage open discussion • Make sure the patient understands what health coaching is • Allow the patient to develop a foundational conception of goal setting and action planning • The patient creates (SMART) measurable, action-based, realistic and timely achievable goals • Have better control of carbohydrate and fat intake • Gradually increase physical activity • Gradually increase achievable tasks until the intended behaviour is achieved	• Education • Enablement • Training • Restriction • Environmental restructuring

Table 2. *Cont.*

Phase #	Session Content	Session Goals	Intervention Function
2	• Phase #2 (session # 2), (this phase will be used again in sessions # 4 and 5) • Check ongoing progress • Understand patient's state (use reflections) • Ask patient to share views (so far) of good things that occurred and experiences from last session • Use positive reflections about patient's strengths, passion or emotions • Ask patient to assess the previously selected short goals and accomplishments • Use reflections to understand potential barriers prevent patient from achieving past goals • Identify specific strategies that they may use to overcome the obstacles • Explore what patient learned from past experience • Ask and discuss with patient next short goals • Share feedback on patient's progression • Ask patient to connect current accomplishments to the general 3-months goals • Review the general goals to see if patient want to revise them (to be more realistic and achievable) • Affirm the patient's choices, strengths, and capability • Use techniques such as reflective listening to address ambivalence and respond to the patient's resistance (motivational interviewing)	• Assessment of progression • Review goal setting (behaviour) • Review behaviour goals to examine a patient's performance progression toward the agreed goals • Enable patient to develop problem-solving skills • Enable patient to create action plan • Prompt the participant to generate ideas and strategies to overcome barriers (problem-solving) • Allow patients to monitor their behaviours (know the changes so far) • Keep patient motivated (no matter the accomplishments)	• Persuasion • Education • Enablement • Training • Restriction • Environmental restructuring

Table 2. *Cont.*

Phase #	Session Content	Session Goals	Intervention Function
3	• Middle phase (session # 3), the coach continues to observe the patient and give feedback to help them move forward in achieving their goals through bi-weekly SMART goal setting. • Patient continues to identify strategies to address existing obstacles and enhance their self-ability • If goals are not achieved, the barriers will be identified, action plan will be taken to address these obstacles and modified goals will be created • The coach will assess the patient's self-efficacy by scoring goals to measure the participant's confidence in achieving their goals • The coach continues using the skills needed to explore ambivalence and discrepancies between the participant's plans and their actual behaviour (Rollnick et al., 2005) • Affirmations and appreciative inquiry will be used to appreciate progression and improve patients' self-confidence	• Assessment of current behavioural change • Review goal setting (behaviour) • Review behaviour goals to examine a patient's performance progression toward the agreed goals • Review all previous goals and reassess goal progress • Enable the participant to assess their progress • Prompt the participant to analyse factors influencing their behaviour • Participant's commitment to affirm to review and change behaviour	• Persuasion • Education • Enablement • Training
4	• (session # 6) • Conclude the coaching relationship • Determine where the patient is in terms of their goals • How the coach can best guide the client, and whether coaching is what will best benefit the client • Participants' assessment of the intervention, general satisfaction of the participant with the process • Appreciate the patient's engagement in the intervention • Explore the patients' experience and how future coaching intervention would best support T2DM	• Allow patient to explore the difference at the endpoint • Learn for participants' experience • Findings from the feasibility study will be used to justify an expansion of the study (full-scale) or refined for better outcomes so that we can carry out a large RCT on the efficacy of this intervention	• Persuasion • Education

In summary, a total of 29 BCTs will be used to carry out the content of health coaching, including the activities to achieve the desired outcomes. Out of 29 BCTs, 16 BCTs were identified from the intervention underpinning theories (IM and TTM) [40,41]. In addition, four BCTs were identified and showed effectiveness in reducing the levels of HbA1c [42]. Additional nine BCTs were included that match the provided skills of health coaching.

2.8.2. Intervention Procedure

Three trained and qualified health coaches will deliver the coaching sessions. They all will receive training on the intervention curriculum (see Table 2). Additionally, they will be monitored by the researchers throughout the period of delivery of the intervention. The intervention consists of 6 sessions that will be delivered biweekly via face-to-face meetings and telephone coaching over a 3-month period. Intervention group participants will be contacted fortnightly and coached using a combination of different methods; in person, by phone, and by smartphone (e.g., secure messaging such as WhatsApp) while the control group participants only receive the usual care for participants with T2DM with includes general lifestyle advice. Face-to-face coaching is only conducted at baseline and in the third month of the intervention for 30–45 min coaching sessions. In addition, 10–15 min telephone coaching will be delivered for the other four sessions (see Figure 1).

Figure 1. Health coaching intervention sessions biweekly.

The health coach works as an ally to enable participants to effectively engage in their self-care needs and address potential self-management barriers. They will be provided with different tools, including a patients' progress tracker, coach notes log and a coaching log to help them run each coaching session. Participants will be given the opportunity to learn and practice significant skills to help them reach target goals through action plans they set for themselves for better self-care [43]. Table 2 illustrates the operationalised protocol and phases of session delivery

2.8.3. Usual Care (Control Group)

Control group participants will receive only the usual care. Standard care includes providing written information on diabetes and brochures for raising awareness, including the benefits of modifying their health behaviours. Generally, T2DM patients have regularly scheduled visits to check diabetes management by endocrine specialists. The visit's main purpose is to check whether the patient's medications need to be replaced, increased, or continue with the same prescription.

2.9. Measures

Different tools and measures will be used to assess the primary and secondary study's outcomes as presented in below sections. To reduce the risk of bias, an independent interviewer will be trained and supervised by the researchers to undertake the role of collecting some data, including semi-structured interviews and providing questionnaires. The interview guide will be developed by the researchers and used by the interviewer to guide the interviews. The interviewer will remain blind to the intervention details, process, and activities. Control group participants will be requested to complete pre- and post-intervention measures and questionnaires.

2.9.1. Primary Outcome Measures

Feasibility

The primary outcome will assess the feasibility, including recruitment rates of the study and retention, and acceptability of the intervention by participants. During this step, the researchers seek to measure the possibility of recruiting sufficient participants within a specific period and the number of recruited participants who completed the study. Participants' responses and expressions of their engagement interests will be recorded, including reasons for interest, reasons for engagement, and reasons for not interest. The number and percentage of interested eligible, complete, and drop-out participants will be recorded to explain the recruitment rates and retention. In addition, the researchers will undertake a qualitative process evaluation to investigate participants' and their physicians' experiences and feedback on the intervention, including assessment of the most appropriate advertising method for the intervention. Different questionnaires will be used to provide further information. In addition, the health coach also will report on his experience with participants.

Acceptability

Qualitative and quantitative data will be used to assess to what extent the intervention and its implementation are acceptable to the patients. The purpose of assessing the implementation process is to identify any potential problem with the methodology used to deliver the intervention. The acceptability of the implementation process, including data collection procedures, will be assessed by conducting post-intervention semi-structured qualitative interviews, informal meetings and focus groups. Interview guidance will be used to direct the conversations and enable the researchers to explore more details about how the participants find and describe their intervention experience. A questionnaire will be used to quantify the participants' self-reported satisfaction (Likert-scale Satisfaction Questionnaire, 14-items). Healthcare providers and participants' opinions are important to help adapt the intervention in terms of ensuring that it corresponds with and is acceptable for the Saudi cultural context.

2.9.2. Secondary Outcome Measures

The secondary outcomes (preliminary efficacy) comprise anthropometric, clinical, and psychological variables selected as of the standard measures for monitoring and prevention of complications in diabetes [44]. These variables will be assessed twice at the intervention, at baseline and after 3 months for HbA1C, blood pressure, body mass index (BMI), weight and waist circumference. Change in outcomes post-intervention will help to determine if the intervention is feasible, acceptable, and effective. Table 3 provides the timeline for the assessment of the variables.

2.9.3. Demographic Information

Demographic information will be used to explain the nature of the recruited participants in the intervention. It will be collected at a single time during the intervention baseline.

2.9.4. Fidelity Assessment

Qualitative data, including interviews, focus groups, meetings, and coaching sessions will be audio recorded, transcribed, and translated into English. Thematic analysis will be used to analyse qualitative data. Multiple audio recorders will be used to ensure high reliability, and they will be transcript to text by two independent native Arabic speakers. Final coding will be used after reaching an agreement between the independent transcribers. Translation to English will be the next step completed by the researchers and an additional check of meaning by an independent native Saudi Arabian Arabic speaker.

Table 3. Timeline for the assessment of the intervention measurements.

Study Timeline				
Pre-Study Allocation			**Post-Study Allocation**	
Activity	**Enrolment**	**Allocation**	**Baseline**	**Endpoint**
Intervention advertising				
Screening eligibility				
Informed consent				
Baseline measures				
Randomisation				
Allocation				
Start of the Study:				
Intervention group				
Control group				
Assessments:				
Demographic				
BMI				
Weight				
Blood pressure				
Waist circumference				
HbA1c				
Feasibility Questionnaire				
Summary of Diabetes Self Care Activity (SDSCA), 12-items				
Self-efficacy Scale for Diabetes, 8-items				
Acceptibity Questionnaire				
Likert Scale Satisfaction Questionnaire, 14-items				

2.9.5. Predetermined Progression Criteria to Proceed to a Larger Trial

Before the feasibility of RCT started, the research team developed progression criteria. The progression criteria will help to decide on carrying out a full scale based on the findings generated from the feasibility study regarding recruitment, retention, adherence, and overall acceptability [45]. These criteria establish the benchmarks for assessing the trial's feasibility and determining whether undertake a further larger-scale study. The predetermined progression criteria are presented in Table 4.

Table 4. Health coaching predetermined criteria.

Criteria	Predetermined Cut-Offs
Screening prospective participants	• If 60–80% or more of those eligible to participate in the study consented, this supports conducting a large RCT scale trial, but if percentage is less than 50%, there is no significance to move forward.
Recruitment rate	• If the recruitment rate of people who were eligible and consented was ≥80% this would support conducting a large RCT trial. • If the rate was between 70–65%, this needs further discussion to explore the reasons and whether, if they can be modified, then the trial may progress with cautions. • If the rate was ≤65%, there is no significance to moving forward.
Retention rate at 3-months	• If the rate was ≥83%, this supports conducting a large RCT scale trial • If the rate was less than 83%, there is no significance to moving forward.
Intervention adherence	• If the adherence rate was ≥84% of the intervention (≥5 out of the 6 coaching sessions) • If the rate was between 84–67% (≥5.4 out of the 6 coaching sessions), this needs further discussion to explore the reasons and whether, if they can be modified, then the trial may progress with cautions. • If the adherence rate was less than 67%, there is no significance to moving forward.

2.9.6. Data Management

Both textual and audio data will be generated and collected using different research methods. The textual data are (i) clinical observations and field notes; (ii) notes collected from formal and informal meetings with healthcare staff; and (iii) field notes from the health coaching sessions. The audio data will consist of (i) recordings of some formal and informal meetings with healthcare professionals; (ii) recordings from health coaching sessions; and (iii) recordings from focus groups. All recordings will be immediately downloaded on separate devices.

The majority of raw quantitative data will be stored as tabular data copies in Microsoft Excel format to allow for statistical analysis via (SPSS). Thematic analysis will be used to analyse qualitative data. Multiple audio recorders will be used to ensure high reliability, and they will be transcript to text by independent native Saudi speakers. Qualitative data will be stored temporarily on multiple hard drives, e.g., USB and Google Drive, and manual copies, e.g., handbooks and logbooks. Separate files will be used for each type of qualitative data for organising purposes. For ensuring the long-term usability of data, they will be stored in a secure place within (KFMC governmental institution) for confidentiality purposes and participants' privacy. Additional space storage will be requested from the University of Sheffield to ensure that enough multiple copies of data are there in case of any potential risk, for example, losing some data due to storage abilities or difficulty in accessing any other technical issues. I will continuously make backups of the files on external hard devices and in a safe and secure place through (KFMC and the University of Sheffield).

Qualitative data, including interviews, focus groups, meetings, and coaching sessions will be recorded on electronic recorders, transcribed, and translated. There will be interview guidance used to direct the conversations and enable the researchers to obtain the

intervention's information. All participants will be given a unique reference number used when referring directly to their responses. Quantitative data will be generated and collected by the researchers with support from the centre's health professionals, including HbA1c, BMI, blood pressure, weight and waist circumference. All data will be encrypted using a high-level encryption method to protect collected data (using FileVault on Mac) and the University Data Centre.

The researchers will be monitoring the quality of data from the beginning until the intervention endpoint. Data will be organised based on its type (e.g., interviews, coaching sessions, etc.), in separate files within one folder for easy access to each type at any time. Multiple copies of the folder will be backed up and stored throughout the period of data collection. Backups with up-to-date data will be completed continuously to keep data safe and updated. Qualitative data will be recorded to avoid accidentally missing information. This would allow for assessing the consistency and quality of the data collected. Vitro measures will be taken by a health practitioner (e.g., laboratory specialist) from KFMC in Riyadh. Multiple samples will be taken to ensure the quality of results by comparison.

3. Data Analysis

3.1. Quantitative Data

The feasibility and acceptability of the study's findings will be evaluated in relation to the quantitative data using descriptive analysis. The descriptive analysis covers different aspects as the following:

- Screening, recruitment process, retention and adherence (coaching sessions) rates will be calculated and presented as proportions
- Length of time to recruit the target sample
- Duration of time needed to complete the assessments
- Percentage of completed interventions sessions
- Average time needed to complete each session
- Description of participants interaction during coaching sessions (frequent BCTs used, interactions with coaches)
- Acceptability and suitability of intervention through participants' perceptions of, and experiences with, the health coaching intervention (Satisfaction Questionnaire)
- Additionally, other outcome measures such as diabetes self-management and patient self-efficacy will be evaluated at baseline and endpoint to investigate changes in participants' behaviours compared to another group
- Preliminary effects of the intervention
- Regarding the evaluation of the preliminary efficacy of the intervention, secondary variables will be described by means and S.Ds, investigated pre- and post-intervention to measure changes in the outcomes; glycosylated haemoglobin (HbA1C), blood pressure, body mass index (BMI), waist circumference, weight, patients' self-efficacy, and diabetes self-management
- Correlations will be performed between:
- The number of completed coaching sessions and A1c, BP, BMI, WC body weight at 3 months
- The number of completed coaching sessions and self-efficacy and diabetes self-management scales at 3 months

3.2. Qualitative Data

Qualitative data, including interviews, focus groups, meetings, and coaching sessions will be audio recorded then transcribed, and translated into English. Thematic analysis will be used to analyse qualitative data. Multiple audio recorders will be used to ensure high reliability, and they will be transcript to text by independent native Saudi Arabian speakers. The qualitative analysis includes the following:

All interviews and focus groups are recorded and transcribed

- A total of 10% of transcription will be translated from Arabic to English, back-translated for accuracy and validity purposes, and checked by a professional native speaker.

To prevent meaning from being lost in translation, to improve the validity of the data, which might be compromised if it is translated, and to expedite the process, the analysis will be carried out in the original language [46].

- The analysis will be conducted by using:
  - o A reflexive thematic analysis [47];
  - o From a Pragmatic philosophical standpoint [48];
  - o Thematic analysis will be manually conducted using NVivo software.

Next, all interactions with the health coaches through the coaching sessions will be mapped to the BCW and the BCTTv1 using NVivo for coding used BCTs. The final step is integrating QUALI and QUANT data and analysing them as they occurred concurrently simultaneously per the thesis process diagram (convergent design).

4. Discussion

Changing lifestyle is widely recognised as the key to supporting people with T2DM to adopt healthy behaviours to control their condition. An individualised, self-management approach for non-communicable diseases such as T2DM is now urged to a more prominent degree than at any other time [49,50]. Several studies have reported the positive effects of lifestyle intervention programmes among people at high-risk, with a 58% decrease in the incidence of T2DM [51,52]. Utilising a lifestyle intervention aims at reducing the probable risks of chronic diseases in addition to decreasing the occurrence of such conditions, if already existent, as part of a management plan. Adopting a healthy diet accompanied by physical activity is likely to decrease the risk of T2DM by 45% regardless of genetic risk [11]. Different studies have found that chronic diseases such as T2DM can be effectively addressed using health coaching programmes, which aim to promote healthy behaviours [53]. Moreover, studies have demonstrated the effectiveness of health coaching with a variety of chronic illnesses, including T2DM [21].

Conducting the feasibility study will help inform the research development process by identifying key uncertainties in the study before a future full-scale intervention is carried out. It is hoped that the findings of the present study will contribute to informing the research field of health coaching on T2DM and to ensure the intervention achieves a good fit with a new context; namely, Saudi patients with T2DM. Since health coaching as a new approach is now included in the Saudi Ministry of Health's (MOH) future plans, the study findings can directly inform future policy developments in SA. Additionally, it is hoped that the present study will make a significant contribution to the literature as it represents the first study that has been developed based on the use of specific "active ingredients" (BCTs), which directly match the intervention's underpinning theories. Consequently, health coaching intervention designers may benefit from the study's findings by allowing them to interpret and identify effective BCTs to facilitate future replication. Finally, the study's findings could lead to the increased uptake of other behaviour change interventions in the Saudi Arabian context.

Supplementary Materials: The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/ijerph192215089/s1, File S1: CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial, File S2: BCTs matching the motivational interviewing, partly adopted from Hardcastle et al. (2017) [40], File S3: BCTs matching the stage of change model, partly adapted from Moore et al. (2015) [41].

Author Contributions: Conceptualization, A.N.A.; methodology, A.N.A.; software, A.N.A.; validation, A.N.A.; resources, A.N.A.; data curation, A.N.A.; writing—original draft preparation, A.N.A.; writing—review and editing, A.N.A., E.G. and S.J.C.; visualization, A.N.A.; supervision, E.G. and S.J.C.; funding acquisition, A.N.A. All authors have read and agreed to the published version of the manuscript.

Funding: This study received no external funding.

Institutional Review Board Statement: Ethical approval was obtained by the University of Sheffield and the Institutional Review Board (IRB) committee form ethical approval at (KFMC) (IRB Log Number: 21-062E).

Informed Consent Statement: Prior to data collection, written informed consent from participants will be obtained.

Data Availability Statement: All data generated or analysed during this study will be included and are available upon reasonable request from the corresponding author.

Acknowledgments: We would like to thank the University of Sheffield Institutional Open Access Fund for its support. This paper will be published under a Creative Commons Attribution (CC BY) licence.

Conflicts of Interest: The authors declare no conflict of interest.

References

1. *Global Report on Diabetes WHO Library Cataloguing-in-Publication Data Global Report on Diabetes*; WHO Press: Geneve, Switzerland, 2016.
2. Complications of Diabetes. Available online: https://www.diabetes.org.uk/guide-to-diabetes/complications (accessed on 4 April 2022).
3. IDF Diabetes Atlas Tenth Edition 2021. Available online: https://www.idf.org/aboutdiabetes/what-is-diabetes/facts-figures.html (accessed on 4 April 2022).
4. Diabetes. Available online: https://www.who.int/news-room/fact-sheets/detail/diabetes (accessed on 13 April 2022).
5. Al Slamah, T.; Nicholl, B.I.; Alslail, F.Y.; Melville, C.A. Self-management of type 2 diabetes in gulf cooperation council countries: A systematic review. *PLoS ONE* **2017**, *12*, e0189160. [CrossRef] [PubMed]
6. Alqurashi, K.A.; Aljabri, K.S.; Bokhari, S.A. Prevalence of diabetes mellitus in a Saudi community. *Ann. Saudi Med.* **2011**, *31*, 19–23. [CrossRef] [PubMed]
7. Liu, J.; Ren, Z.H.; Qiang, H.; Wu, J.; Shen, M.; Zhang, L.; Lyu, J. Trends in the incidence of diabetes mellitus: Results from the Global Burden of Disease Study 2017 and implications for diabetes mellitus prevention. *BMC Public Health* **2020**, *20*, 1415. [CrossRef]
8. Al-Rubeaan, K. National surveillance for type 1, type 2 diabetes and prediabetes among children and adolescents: A population-based study (SAUDI-DM). *J. Epidemiol. Community Health* **2015**, *69*, 1045–1051. [CrossRef] [PubMed]
9. Alanazi, F.K.; Alotaibi, J.S.; Paliadelis, P.; Alqarawi, N.; Alsharari, A.; Albagawi, B. Knowledge and awareness of diabetes mellitus and its risk factors in saudi arabia. *Saudi Med. J.* **2018**, *39*, 981–989. [CrossRef] [PubMed]
10. Azab, A.S. Glycemic control among diabetic patients. *Saudi Med. J.* **2001**, *22*, 407–409. [PubMed]
11. Midhet, F.M.; Al-Mohaimeed, A.A.; Sharaf, F.K. Lifestyle related risk factors of type 2 diabetes mellitus in Saudi Arabia. *Saudi Med. J.* **2010**, *31*, 768–774.
12. Gillies, C.L.; Abrams, K.R.; Lambert, P.C.; Cooper, N.J.; Sutton, A.J.; Hsu, R.T.; Khunti, K. Pharmacological and lifestyle interventions to prevent or delay type 2 diabetes in people with impaired glucose tolerance: Systematic review and meta-analysis. *BMJ* **2007**, *334*, 299. [CrossRef]
13. Wolever, R.Q.; Jordan, M.; Lawson, K.; Moore, M. Advancing a new evidence-based professional in health care: Job task analysis for health and wellness coaches. *BMC Health Serv. Res.* **2016**, *16*, 205. [CrossRef]
14. Wroth, S.W. Health Coaching Bridges Gaps in Patient Care. *Altern. Complement. Ther.* **2015**, *21*, 157–159. [CrossRef]
15. Newman, S.; Steed, L.; Mulligan, K. Self-management interventions for chronic illness. *Lancet* **2004**, *364*, 1523–1537. [CrossRef]
16. Aikaterini, T.; Papazafiropoulou, A.K.; Melidonis, A. Type 2 diabetes and quality of life. *World J. Diabetes* **2017**, *8*, 120–129.
17. Alabdulbaqi, D. A Cultural Adaptation of a Diabetes Self-Management Programme for Patients with Type 2 Diabetes Attending a Primary Health Care Centre in Saudi Arabia. Ph.D. Thesis, London School of Hygiene & Tropical Medicine, London, UK, April 2019.
18. Pearson, M.L.; Mattke, S.; Shaw, R.; Ridgely, M.M.S.; Wiseman, S.H. *Patient Self-Management Support Programs: An Evaluation*; Final Contract Report Agency for Healthcare Research and Quality: Rockville, MD, USA, 2007.
19. Wolever, R.Q.; Dreusicke, M.; Fikkan, J.; Hawkins, T.V.; Yeung, S.; Wakefield, J.; Duda, L.; Flowers, P.; Cook, C.; Skinner, E. Integrative Health Coaching for Patients With Type 2 Diabetes. *Diabetes Educ.* **2010**, *36*, 629–639. [CrossRef] [PubMed]
20. Wong-Rieger, D.; Rieger, F.P. Health coaching in diabetes: Empowering patients to self-manage. *Can. J. Diabetes* **2013**, *37*, 41–44. [CrossRef] [PubMed]
21. Pirbaglou, M.; Katz, J.; Motamed, M.; Pludwinski, S.; Walker, K.; Ritvo, P. Personal Health Coaching as a Type 2 Diabetes Mellitus Self-Management Strategy: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. *Am. J. Health Promot.* **2018**, *32*, 1613–1626. [CrossRef]
22. Hill, B.; Richardson, B.; Skouteris, H. Do we know how to design effective health coaching interventions: A systematic review of the state of the literature. *Am. J. Health Promot.* **2015**, *29*, e158–e168. [CrossRef]
23. Michie, S.; van Stralen, M.M.; West, R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implement. Sci.* **2011**, *6*, 42. [CrossRef]

24. Alamri, F.; Radwan, N.; Elolemy, A.; Alkhashan, H. Effectiveness of health coaching on diabetic patients: A Systematic Review and Meta-analysis. *Tradit. Med. Res.* **2019**, *4*, 314–325.
25. Davies, M.J.; Heller, S.; Skinner, T.C.; Campbell, M.J.; Carey, M.E.; Cradock, S.; Dallosso, H.M.; Daly, H.; Doherty, Y.; Eaton, S.; et al. Effectiveness of the diabetes education and self management for ongoing and newly diagnosed (DESMOND) programme for people with newly diagnosed type 2 diabetes: Cluster randomised controlled trial. *BMJ* **2008**, *336*, 491–495. [CrossRef]
26. van Bokhoven, M.A. Designing a quality improvement intervention: A systematic approach. *Qual. Saf. Health Care* **2003**, *12*, 215–220. [CrossRef]
27. Craig, P.; Dieppe, P.; Macintyre, S.; Michie, S.; Nazareth, I.; Petticrew, M. Developing and evaluating complex interventions. *BMJ* **2008**, *337*, a1655. [CrossRef]
28. Bowen, D.J.; Kreuter, M.; Spring, B.; Cofta-Woerpel, L.; Linnan, L.; Weiner, D.; Bakken, S.; Kaplan, C.P.; Squiers, L.; Fabrizio, C.; et al. How We Design Feasibility Studies. *Am. J. Prev. Med.* **2009**, *36*, 452–457. [CrossRef] [PubMed]
29. Michie, S.; Prestwich, A. Are interventions theory-based? Development of a theory coding scheme. *Health Psychol.* **2010**, *29*, 1–8. [PubMed]
30. Eldridge, S.M.; Chan, C.L.; Campbell, M.J.; Bond, C.M.; Hopewell, S.; Thabane, L.; Lancaster, G.A.; Altman, D.; Bretz, F.; Campbell, M.; et al. CONSORT 2010 statement: Extension to randomised pilot and feasibility trials. *BMJ* **2016**, *355*, i5239. [CrossRef]
31. Powell, H.; Mihalas, S.; Onwuegbuzie, A.J.; Suldo, S.; Daley, C.E. Mixed methods research in school psychology: A mixed methods investigation of trends in the literature. *Psychol. Sch.* **2008**, *45*, 291–309. [CrossRef]
32. Hariton, E.; Locascio, J.J. Randomised controlled trials—The gold standard for effectiveness research: Study design: Randomised controlled trials. *BJOG* **2018**, *125*, 1716. [CrossRef]
33. Schulz, K.F.; Altman, D.G.; Moher, D. CONSORT 2010 Statement: Updated guidelines for reporting parallel group randomised trials. *BMJ* **2010**, *340*, 698–702. [CrossRef]
34. Cocks, K.; Torgerson, D.J. Sample size calculations for pilot randomized trials: A confidence interval approach. *J. Clin. Epidemiol.* **2013**, *66*, 197–201. [CrossRef]
35. Julious, S.A. Sample size of 12 per group rule of thumb for a pilot study. *Pharm. Stat.* **2005**, *4*, 287–291. [CrossRef]
36. Atkins, L.; Francis, J.; Islam, R.; O'Connor, D.; Patey, A.; Ivers, N.; Foy, R.; Duncan, E.M.; Colquhoun, H.; Grimshaw, J.M.; et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. *Implement. Sci.* **2017**, *12*, 77. [CrossRef]
37. Dyson, P.A.; Twenefour, D.; Breen, C.; Duncan, A.; Elvin, E.; Goff, L.; Hill, A.; Kalsi, P.; Marsland, N.; McArdle, P.; et al. Diabetes UK evidence-based nutrition guidelines for the prevention and management of diabetes. *Diabet. Med.* **2018**, *35*, 541–547. [CrossRef] [PubMed]
38. Michie, S.; Ashford, S.; Sniehotta, F.F.; Dombrowski, S.U.; Bishop, A.; French, D.P. A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: The CALO-RE taxonomy. *Psychol. Health* **2011**, *26*, 1479–1498. [CrossRef] [PubMed]
39. Van Vugt, M.; De Wit, M.; Cleijne, W.H.J.J.; Snoek, F.J. Use of behavioral change techniques in web-based self-management programs for type 2 diabetes patients: Systematic review. *J. Med. Internet Res.* **2013**, *15*, e279. [CrossRef] [PubMed]
40. Hardcastle, S.J.; Fortier, M.; Blake, N.; Hagger, M.S. Identifying content-based and relational techniques to change behaviour in motivational interviewing. *Health Psychol. Rev.* **2017**, *11*, 1–6. [CrossRef] [PubMed]
41. Moore, M. *Coaching Psychology Manual*, 2nd ed.; Lippincott Williams and Wilkins: St. Baltimore, MD, USA, 2015.
42. Cradock, K.A.; ÓLaighin, G.; Finucane, F.M.; Gainforth, H.L.; Quinlan, L.R.; Ginis, K.A.M. Behaviour change techniques targeting both diet and physical activity in type 2 diabetes: A systematic review and meta-analysis. *Int. J. Behav. Nutr. Phys. Act.* **2017**, *14*, 18. [CrossRef]
43. Schulman-Green, D.J.; Naik, A.D.; Bradley, E.H.; McCorkle, R.; Bogardus, S.T. Goal setting as a shared decision making strategy among clinicians and their older patients. *Patient Educ. Couns.* **2006**, *63*, 145–151. [CrossRef]
44. International Diabetes Federation: Daibetes—Facts & Figures. 2005. Available online: https://www.idf.org/aboutdiabetes/what-is-diabetes/facts-figures.html (accessed on 13 April 2022).
45. Avery, K.N.; Williamson, P.R.; Gamble, C.; Francischetto, E.O.C.; Metcalfe, C.; Davidson, P.; Williams, H.; Blazeby, J.M. Informing efficient randomised controlled trials: Exploration of challenges in developing progression criteria for internal pilot studies. *BMJ Open* **2017**, *7*, e013537. [CrossRef] [PubMed]
46. Smith, H.J.; Chen, J.; Liu, X. Language and rigour in qualitative research: Problems and principles in analyzing data collected in Mandarin. *BMC Med. Res. Methodol.* **2008**, *8*, 44. [CrossRef]
47. Braun, V.; Clarke, V. Using thematic analysis in psychology. *Qual. Res. Psychol.* **2006**, *3*, 77–101. [CrossRef]
48. Cherryholmes, C.H. Notes on pragmatism and scientific realism. *Educ. Res.* **1992**, *21*, 13–17. [CrossRef]
49. Lund, S.H.; Aspelund, T.; Kirby, P.; Russell, G.; Einarsson, S.; Palsson, O.; Stefánsson, E. Individualised risk assessment for diabetic retinopathy and optimisation of screening intervals: A scientific approach to reducing healthcare costs. *Br. J. Ophthalmol.* **2016**, *100*, 683–687. [CrossRef] [PubMed]
50. Powell, C.K.; Hill, E.G.; Clancy, D.E. The Relationship Between Health Literacy and Diabetes Knowledge and Readiness to Take Health Actions. *Diabetes Educ.* **2007**, *33*, 144–151. [CrossRef] [PubMed]

51. Knowler, W.C.; Barrett-Connor, E.; Fowler, S.E.; Hamman, R.F.; Lachin, J.M.; Walker, E.A.; Nathan, D.M.; Watson, P.; Mendoza, J.; Smith, K. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N. Engl. J. Med.* **2002**, *346*, 393–403. [PubMed]
52. Lindstrom, J. Sustained reduction in the incidence of type 2 diabetes by lifestyle intervention: Follow-up of the Finnish Diabetes Prevention Study. *Lancet* **2006**, *368*, 1673–1679. [CrossRef]
53. Gallé, F.; Di Onofrio, V.; Cirella, A.; Di Dio, M.; Miele, A.; Spinosa, T.; Liguori, G. Improving Self-Management of Type 2 Diabetes in Overweight and Inactive Patients Through an Educational and Motivational Intervention Addressing Diet and Physical Activity: A Prospective Study in Naples, South Italy. *Diabetes Ther.* **2017**, *8*, 875–886. [CrossRef] [PubMed]

Supplementary File 1:

Supplementary File S1

CONSORT 2010 checklist of information to include when reporting a pilot or feasibility trial[31]

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	1
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	2–4
	2b	Specific objectives or research questions for pilot trial	4
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
	4c	How participants were identified and consented	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5–7
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	18

	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	NA
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	19–20
Sample size	7a	Rationale for numbers in the pilot trial	5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	19–20
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	5
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	4
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	20–21
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	NA
	13b	For each group, losses and exclusions after randomisation, together with reasons	NA
Recruitment	14a	Dates defining the periods of recruitment and follow-up	NA
	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	NA
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	NA

Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	NA
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
	19a	If relevant, other important unintended consequences	NA
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	NA
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	NA
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	NA
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	NA
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	NA
Protocol	24	Where the pilot trial protocol can be accessed, if available	NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	NA
	26	Ethical approval or approval by research review committee, confirmed with reference number	4

Supplementary File 2: S2

Supplementary File S2

Table 10. BCTs matching the motivational interviewing, partly adopted from Hardcastle et al., (2017) [41]

MI Technique	Example of Technique	BCTs from Michie et al.'s (2013) taxonomy
ENGAGING TECHNIQUES:		
Affirmation	Despite the fact that things didn't go as you had hoped, your intentions were good."	15.1: Verbal persuasion about capability
FOCUSING TECHNIQUES:		
Elicit-Provide Elicit	"What do you know about type II diabetes? "	5.1: Information about health consequences
EVOKING TECHNIQUES:		
Running Head Start	"What advantages might a change in lifestyle bring?"	9.2: Pros and cons
Looking Forward	"What may occur if the current situation is maintained?"	9.3: Comparative imagining of future outcomes
Hypothetical thinking	"What steps would you take if you did decide to alter your behaviour?"	15.2: Mental rehearsal of successful performance
Query Extremes	"What do you think would be the BEST outcome from this change?"	5.5: Salience of consequences
Identify Past Successes	"What have you discovered after trying to change in the past?"	15.3: Focus on past success
Identify Strengths	"Tell me about your key strengths?"	13.4: Valued self-identity

Troubleshooting	"Imagine supposing there wasn't this one significant roadblock. How might you go about implementing this change if that barrier were removed?"	1.2: Problem-solving
Values Exploration (open or structured)	"What issues are most crucial to you? or "What is your greatest life goal?" How do your eating habits align with your beliefs and goals?"	13.4: Valued self-identity
Reframing	Change "I'm unable to do it" to "So, you find it challenging to…"	13.2: Framing/reframing
Normalizing	"Most people have both positive and negative effects from altering their [target behaviour]" or "Many people report experiencing similar emotions to yours. They try to lose weight, but they have trouble.	6.2: Social comparison
PLANNING TECHNIQUES:		
Explore Change Expectations	"What would you anticipate happening if you choose that course of action?"	1.3: Goal setting (outcome)
Consider Change Options	"What are the things you could do?"	1.4: Action planning
Develop a Change Plan	What do you intend to do specifically?	1.4: Action planning
Goal attainment Scaling	Rate a weight loss goal on a scale ranging from −3 (most unfavourable outcome): gain 5 kg in one month to +3 (most favourable outcome): lose 5 kg in one month where 0 is the status quo (remain at current weight)	1.5: Review behaviour goal(s)
Support Change/Persistence	"How may I help you?"	3.1: Social support (unspecified)
Offer Emotional support	"I can assume that I would feel the same way if I were going through what you are."	3.3: Social support (emotional)
Review Outcome goal	"How far along are you with your objective?"	1.7: Review outcome goal(s)
Summarise the Plan	"So, you are going to do …"	1.9: Commitment

Supplementary File 3: S3

Supplementary File S3

Table 11. BCTs matching the *stage of change model*, partly adapted from Moore et al., (2015) [42]

Stage	Health coaching Skills to use	Matched with BCTs
Pre-contemplation	Empathy	3.3: Social support (emotional)
	Sharing	3.1: Social support (unspecified)
	Acceptance	13.4: Valued self-identity
	Affirming	15.1: Verbal persuasion about capability
	Reframing	13.2: Framing/reframing
	Sorting barriers	1.2: Problem-solving
Contemplation	Affirming	15.1: Verbal persuasion about capability
	Sharing	3.1: Social support (unspecified)
	Brainstorming/Sorting barriers	1.2: Problem-solving
	Motivating	10.2: Social reward 3.1: Social support (unspecified)
	Self-Efficacy and Self-Esteem:	
	Verbal persuasion	15.1: Verbal persuasion about capability 15:4 Self-talk
	Vicarious experience	6.2: Social comparison
Preparation	Committing	1.9: Commitment
	Identifying steps	1.1 Goal setting (behaviour)
	Explore change expectations	1.3: Goal setting (outcome)

	Identifying potential obstacles	1.2: Problem-solving
	Values Exploration	13.4: Valued self-identity
Action	Having a plan	1.4: Action planning
	Reframing	13.2: Framing/reframing
	Tracking progress	1.7: Review outcome goal(s)
	Normalising	6.2: Social comparison
	New network	3.1: Social support (unspecified)
	Preparing for lapses/facing obstacles	1.2: Problem-solving
Maintenance	Maintaining the network	3.1: Social support (unspecified)
	Valuing achievements	9.3: Comparative imagining of future outcomes
	Self-identity	13.1: Identification of self as a role model

Published paper ended

4.3.3 Supplementary methods (for trial protocol)

This section includes additional methods that offer more details beyond what is outlined in the protocol paper. These supplementary methods serve as additional information for the study.

4.3.3.1 Use of Motivational Interviewing and Transtheoretical Model

Selecting the appropriate theoretical framework and BCTs before implementing the intervention is crucial for its effectiveness [148]. MI is one of the most commonly used frameworks in health coaching interventions. The previously mentioned review showed that MI has been utilised in 9 studies [149]. Studies have shown that using MI alongside health coaching has resulted in a significant reduction in diabetes levels [4 23]. The TTM model is also frequently used by health coaches to monitor patients' progress throughout an intervention. This model provides a tool for helping to identify each client's respective stage in relation to the target health behaviour [150 151]. MI is commonly incorporated within the application of TTM and is often combined with value-oriented interventions to encourage and support clients to advocate for their own change [112]. This study will incorporate both MI and TTM and integrate them with active BCTs. This approach enables a thorough evaluation of the intervention's effectiveness and facilitates an examination of the elements that worked well and those that did not.

4.3.3.2 Questionnaires

Three questionnaires will be used at the baseline and the endpoint of the intervention; these are as follows: (i) Summary of Diabetes Self Care Activity (SDSCA) (see Appendix 2); (ii) Self-efficacy Scale for Diabetes (see Appendix 3); and (iii) Likert-scale Satisfaction Questionnaire (see Appendix 4).

4.3.3.3Summary of Diabetes Self-Care Activities (SDSCA) scale

This scale will be used to explore the ability of participants to adhere to the advised T2DM self-management behaviours. The SDSCA scale was developed by Toobert, Hampson and Glasgow (2000)[152]. The SDSCA comprises 12-items that evaluate diabetes-related activities such as diet and exercise (see Appendix 2). The participant needs to answer questions to explore to what extent he/she has adhered to self-management activities in the past seven days. Answers ranged from "0", referring to very poor adherence, to "7", which means perfect behaviour adherence [152]. This scale used means and SDs to calculate the average scores for each question [152].

The SDSCA, a scale that is widely recognised and frequently used in research to evaluate diabetes self-care, has consistently demonstrated reliability and validity across diverse contexts [153] [154]. It has shown its effectiveness in various countries and languages, such as English [152], German [154], Turkish [155], Korean [156], serving a range of ethnic populations [157].

The Arabic translation of the SDSCA has also proven its efficacy and has been recognised as suitable and extensively employed across various Arabic contexts. For instance, it has been used in two separate studies in SA where it demonstrated a Cronbach's alpha of 0.76 [158] [159], and in Jordan with a Cronbach's alpha of 0.61[160]. It has also been effectively applied in Lebanon, where it yielded a Cronbach's alpha of 0.86 [161]. In these diverse settings, the questionnaire has consistently showcased its appropriateness and reliability, thereby effectively serving individuals with T2DM in these regions. The author provided the necessary permission to use this scale (see Appendix 2).

4.3.3.4 Self-efficacy Scale for Diabetes

The Stanford Self-Efficacy Scale (8-item scale) will be used to measure patients' confidence levels in performing specific tasks [162] (see Appendix 3). The scale's score will be derived by averaging the eight items; a higher mean score indicates greater self-efficacy. All items are

scored on a scale from 1 (not at all confident) to 10 (totally confident)[163]. The scale was developed to evaluate the Diabetes Self-Management of patients. It consists of 8 items that assess the confidence of the participant to do specific activities. The scale has consistently shown its reliability and appropriateness in different Arabic settings, including Jordan and SA[160 164]. For instance, in SA, it exhibited a Cronbach's alpha of 0.86, demonstrating high internal consistency [164]. Similarly, in Jordan, it displayed an adequate internal consistency with a Cronbach's alpha of 0.768 [160]. The reliability and validity of the scale have been demonstrated in different Arabic contexts, indicating its effectiveness in evaluating the self-efficacy of diabetes patients. The use of this scale is unrestricted and does not require any formal permission (see Appendix 3).

4.3.3.5 Likert-Scale Satisfaction Questionnaire

This questionnaire was originally developed by the Dan Abrahams Healthy Living Centre and later adopted by DeJesus et al. (2018)[165]. The scale includes different question styles (open & closed). The Likert scale question responses range from 0 (not at all) to 10 (very much) to capture participants' feedback (see Appendix 4). The first four questions asked participants about their perceptions of the health coaching, how much the intervention helped them in behaviour change, and what components had been most and least helpful. The following items focused on the coaching procedure and asked participants to describe how the intervention helped boost their motivation, to what extent it improved their use of goal-setting and problem-solving techniques, and to what extent it assisted them in getting back on track after hitting roadblocks[165].

Given that this scale has not yet been implemented in any Arabic studies, we intend to undertake its translation into Arabic and pretest it on a smaller subset prior to utilising it for the entire study sample. This translation and pretesting procedure adheres to the guidelines for

instrument translation set by the WHO[166]. Additionally, as the original developers of this questionnaire did not report its reliability, we will assess it within the context of our study to ensure internal consistency. We have received formal permission from the survey developer to use this questionnaire in our intervention (see Appendix 5).

4.3.3.6 Qualitative data

Because interviews and focus groups were thought to be the most appropriate methods to meet the study's objective (4), they will be used as the primary qualitative methods for data collection to give a more in-depth understanding of participants' perceptions and experiences [167]. While interviews allow participants to effectively express themselves and their personal experiences during the intervention using their own words and feelings, focus groups will be used to explore collective perspectives in order to confirm, extend, or enrich understanding and offer different perspectives [168]. Moreover, for a comprehensive understanding of the findings of qualitative analysis, field notes will be employed to explain some aspects of the study and, especially, the study context. Field notes are crucial in building extensive, comprehensive descriptions of the study context, interviews, focus groups, and important contextual data from documents [169].

4.3.3.7 Focus Groups

This study will involve two separate focus groups, one with participants and another with health coaches, to facilitate in-depth conversations. Focus groups have been shown to lead to a better understanding of the attitudes of participants through sharing thoughts and perspectives to encourage further discussions [170]. Moreover, focus groups can also help researchers and practitioners to best adapt interventions to meet the local context and participants' needs. A focus group is an optimal way to produce new ideas that can be difficult to generate by other

means [171]. To identify the uncertainties in this feasibility study, we adapted O'Cathain's (2015) question guidelines to guide the focus groups [172] (see Appendix 8).

4.3.3.8 Interviews

As part of the data collection for the process evaluation, semi-structured interviews will be used pre- and post-intervention to understand participants 'experiences and perceptions of the intervention. The researcher will conduct semi-structured qualitative interviews for the intervention group (n = approximately 5 participants at baseline and 5 participants at three months) to explore the feasibility and sustainability of the intervention and the acceptability of the trial's implementation. To ensure all relevant topics are covered, interview questions were developed to evaluate the participants' experiences, following O'Cathain's (2015) suggestion[172] (see Appendix 9). Participants who drop out will also be interviewed to explore their experiences and reasons for not completing the intervention. Their experiences and opinions are particularly relevant as their feedback can help evaluate the procedures of implementation and hindrances that these participants might have encountered. The use of qualitative methods will also be useful for eliciting participants' opinions regarding the cultural adaptation of this intervention. Quotes and themes that emerge from these interviews will be coded and analysed. Coaching notes will be included in the analysis.

4.3.3.9 Field notes and session recordings

Field notes are the cornerstone of gathering and analysing information from observations [173]. It is crucial that researchers pay more attention to details by taking and recording their notes as soon as possible [174]. Field notes will be digitized into separate devices to secure and access them easily. While the health coach is required to use attentive silence as a core element while delivering the coaching session, all sessions will be audio-recorded for tracking, re-listening, thematic coding, and analysis purposes. By recording the sessions, the health coach can capture

essential details for later note-taking, ensuring no critical information is missed, and it also allows for complete and undistracted engagement during the session itself.

4.3.3.10 Thematic analysis

After verifying the accuracy of the transcriptions, the researcher will thematically analyse the data using the six phases of thematic analysis [175]. The primary objective of the first phase will be to gain an initial understanding by repeatedly reading and becoming more familiar with the transcribed data. Various notes will be collected during this phase to construct an initial picture. Given that all interviews and focus groups will be conducted online, this step of thematic analysis may take longer as it involves reading and listening to build a comprehensive understanding. Capturing participants' body language and emotional state may be challenging; thus, the tone of their voices will be of significant value in this context. Once a general understanding is formed, different codes will be manually generated and prepared for categorization. This phase will involve highlighting various sections of the written transcription.

Once a sufficient number of codes are collected, a revision phase will be undertaken to filter and group them. Following this, the codes will be reviewed again for classification under pre-defined and emergent themes. Mind maps will be used during this phase to visualize codes and how they may be grouped under specific themes and sub-themes.

The fourth step of the analysis involves evaluating the initially emerged themes and sub-themes. Themes will be reviewed and adjusted based on their coherence, clarity, and relevance of the data categorized under each theme [175]. This process may result in combining several themes and sub-themes to create a clear structure and avoid overlap. After the researcher identifies the themes and sub-themes, an independent researcher will review them for validity and accuracy. Discrepancies may arise regarding how some codes relate to one another and

their association with specific themes. As a result, certain codes may be relocated to different themes or merged with others. Any discrepancies will be resolved through discussion until a consensus is reached, in line with the recommendations of Braun and Clarke (2006) [175]. By the end of this phase, different themes and sub-themes will have been identified.

Thematic analysis will then continue to review the themes and sub-themes, ensuring their precise alignment with the research objective (3). During this phase, each theme and sub-theme will be evaluated to ensure they align with the research aim. Consequently, some sub-themes and themes may be refined, and the researcher will be able to designate and define each included theme. The final phase of the process involves composing and producing the report after translating the extracted data into English. Figure 4.1 illustrates how the analysis will be conducted, following the six phases from familiarization with the data to writing and producing the report.

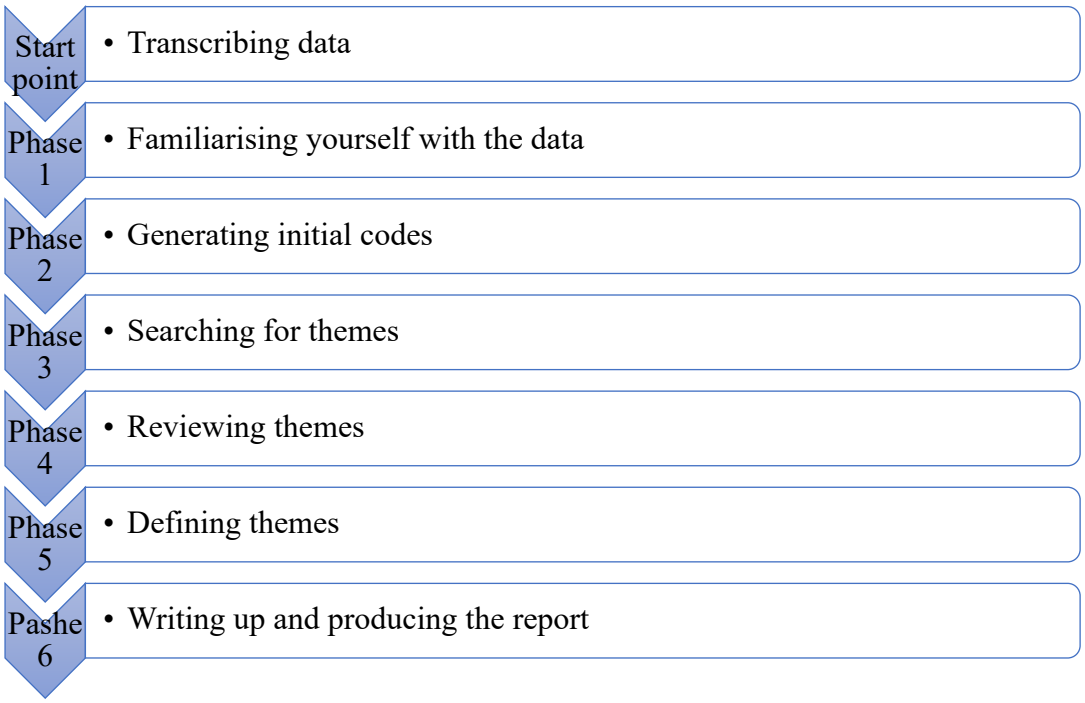

Figure 4-1: Thematic analysis (Adapted from Braun & Clarke, 2006) [175]

4.3.3.11 Statistical analysis

A thorough analysis of the study's quantitative data will be conducted using descriptive analysis to assess the feasibility and acceptability of our findings. This will involve calculating proportions and percentages for various aspects, such as the screening process, recruitment rates, retention rates, and adherence to coaching sessions. We will calculate the proportions and percentages of the completed intervention sessions and determine the average time required for each session. We will also assess the average change pre- and post-intervention for patients' self-efficacy and diabetes self-management by calculating means and SD, comparing changes in participant behaviours to those in a control group. To evaluate the intervention's acceptability, we will use a Likert-scale Satisfaction Questionnaire and calculate the means and SD of the responses. Additionally, as part of the assessment for participant interactions with coaches, we will calculate the number of reported BCTs and the frequency of their usage.

We will assess the initial effectiveness of the health coaching intervention by measuring different variables before and after the intervention, including HbA1C, blood pressure, BMI, weight, and waist circumference. Using a linear regression model, we will estimate the average difference for each outcome while accounting for baseline values.

While the feasibility study may not have sufficient power to detect definitive intervention effects, it will still provide valuable insights. It will assist in estimating the sample size required for a future larger trial by providing information on the mean difference and standard deviation of HbA1c. The data will be entered twice into Microsoft Excel for statistical and descriptive analysis before being transferred to SPSS and STATA. Prior to analysis, we will conduct preliminary checks to ensure normality, linearity, and homogeneity of variances.

4.3.3.12 Integration of qualitative and quantitative data

Integration refers to the interaction between the components of qualitative and quantitative data in research [176]. The joint display table facilitates clear comparisons between the two types of data by visually representing how they are combined. This not only enables integration but also reinforces the validity and transparency of the research [177]. Furthermore, it shows the extent to which data converge, diverge, or one set extends another. Convergence refers to the agreement between the two approaches; divergence refers to disagreement; and expansion refers to when qualitative or quantitative data are found to enhance the other[140]. Convergence helps to use data from both methods to verify each other, reduce the chance of bias and enhance credibility via triangulation [178]. In order to create a thorough knowledge, expansion (complementarity) entails using both data to fill in any gaps left by one of them, providing a more comprehensive understanding [178]. Divergence, on the other hand, allows for exploring inconsistencies between both data sets and using those discrepancies to question each other to generate a dialogue around those contradictions [178]. Finally, employing the convergent design process, both qualitative and quantitative data will be analysed together, as illustrated in the thesis process diagram.

CHAPTER 5: Results

The feasibility study's main objective was to assess the feasibility and acceptability (primary outcomes) of a health coaching intervention for T2DM in SA, including participants' experiences with the intervention and the health coaches' perspectives. The second objective was to examine the preliminary effects of the intervention (secondary outcomes), including HbA1c, blood pressure, BMI, weight and waist circumference, patients' self-efficacy, and diabetes self-management. The feasibility outcomes are presented in the first half of this chapter. The next section presents the secondary outcomes. In the final section of this chapter, qualitative findings from interviews, focus groups, coaching sessions, and field notes are provided.

5.1 Quantitative Results

5.1.1 Feasibility outcomes

5.1.1.2 Eligibility and recruitment

The recruitment for the intervention was planned to take place at King Fahad Medical City (KFMC) in Riyadh, the leader of Riyadh's Second Health Cluster. However, due to unanticipated obstacles due to the COVID-19 pandemic, it was difficult to carry out the recruitment at this place for several reasons; patients were not allowed to have their routine visits to their physicians, physicians were asked to work remotely with their patients, and very limited access to the hospital services including collecting data pre-and post-intervention, e.g., HbA1c. The medical personnel and the research team were strongly advised to carry out their scheduled meetings remotely. It was challenging to get approval to recruit patients under such strict precautions. Moreover, the administration was unable to anticipate a specific time to ease those precautions and allow us to start the recruitment. They, therefore, advised us to recruit

patients from a secondary hospital under their authority. Al-Zulfi general hospital was an optimal option as a part of Riyadh Second Health Cluster, where the patients were allowed to have their routine visits with their doctors. To save time, we decided to collect the sample and carry out the intervention at Al-Zulfi general hospital.

The recruitment process took about five weeks, starting on 1st May 2021 to 5th June 2021. Leaflets were used for advertising the intervention and were distributed in different places in the hospital, including in waiting areas and on hospital wall notice boards. In addition, we met physicians in-person to introduce the intervention and gave them leaflets with more details to encourage their patients to join in the study.

Of the 42 potential participants initially identified and assessed for eligibility, 38 met the study criteria, resulting in a screening rate of approximately 90%. These 42 individuals were referred by different sources. Twenty-two were referred by their doctors, while the others were recruited through various methods. Two were from leaflets, eight were from suggestions by friends or relatives, and ten were directly engaged at the diabetes clinic. Twelve were excluded, of which four were ineligible because they did not meet the intervention inclusion criteria for the following reasons: one had no access to a personal mobile phone/smartphone, one patient was diagnosed with T1DM, one had A1c below 7%, and one was unable to do pre-and post-assessments. Eight were excluded for other reasons; two did not respond, and six for different reasons, e.g., being too busy. Thirty eligible patients were recruited to take part in the intervention. Out of the 38 eligible patients, 30 were successfully recruited and consented to participate in the intervention, yielding a recruitment rate of approximately 79%. All of them completed baseline assessments and questionnaires, and then randomly, 15 patients were allocated to the intervention group, while the other 15 participants were assigned to the control group. One person who was part of the intervention group withdrew from the trial prior to the

first session and was thus not included in the study (see Figure 5.1 CONSORT diagram below for more details)[2].

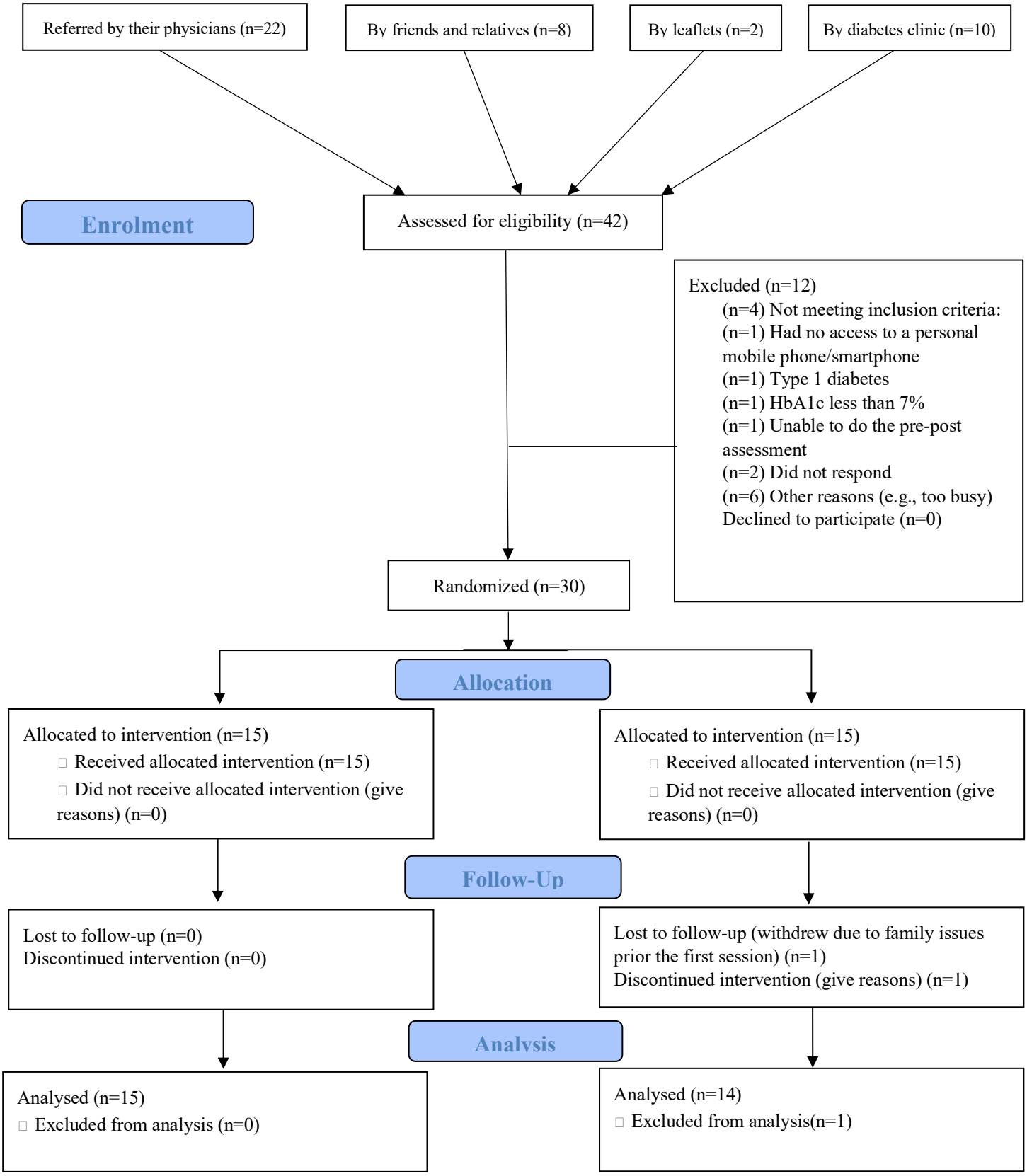

Figure 5-1: CONSORT Flow Diagram of the health coaching RCT[2]

5.1.1.3 Participant characteristics

Sixteen out of the 29 participants recruited to the study were female (55.2%). The sample was aged between 34 and 69 years. The average age of the study participants was 53.66 years, with a standard deviation of 7.92 years and a median of 55 years (IQR: 49 to 59.50 years). When comparing the control group to the intervention group, the average age was slightly higher in the control group (53.40 years), with a standard deviation of 8.47 years, compared to the intervention group (52 years), with a standard deviation of 8.32 years. All participants were married except for one in the control group. The monthly earned income in SR ranged between 5,000 SR and more than 15,000 SR, with a median of 13,000 SR. However, some participants (n=12) preferred not to give an income range. About 24.1% of the sample had completed high school, 20.7% had primary school education, and another 20.7% did not officially study but could read, write, and understand Arabic. About 31% of the sample had T2DM for more than ten years. About 24.7% of participants in the intervention group had lived with T2DM for 1-3 years, 13.8% for 4-7 years, and 24.1% for 7-10 years. Finally, most of the participants (89.7%) used diabetes medications. Table 5.1 provides a summary of the demographic characteristic of both the intervention and control groups.

		Intervention group		Control group	
		Total N (%)	Median (IQR)	Total N (%)	Median (IQR)
Gender	Male	6 (42.9%)		7 (46.7%)	
	Female	8 (57.1%)		8 (53.3%)	
Age	Year	14	54.50 (44.5 to 59.25)	15	54 (50 to 60)
Marital status	Married	14 (100.0%)		14 (93.3%)	
	Single	0 (0.0%)		1 (6.7%)	
Monthly income	less than 5000	4 (28.6%)		7 (46.7%)	
	5000-10000	2 (14.3%)		0 (0.0%)	
	10000-15000	0 (0.0%)		2 (13.3%)	
	more than 15000	1 (7.1%)		1 (6.7%)	
	Prefer not to declare	7 (50.0%)		5 (33.3%)	
Education level	Illiterate	0 (0.0%)		0 (0.0%)	
	Primary school	3 (21.4%)		3 (20.0%)	
	Secondary school	2 (14.3%)		2 (13.3%)	
	High school	3 (21.4%)		4 (26.7%)	
	Bachelor's degree	2 (14.3%)		3 (20.0%)	
	Diploma	1 (7.1%)		0 (0.0%)	
	Can read and write	3 (21.4%)		3 (20.0%)	
Since when you were diagnosed with Type 2 diabetes	less than a year	2 (14.3%)		0 (0.0%)	
	1-3	6 (42.9%)		0 (0.0%)	
	3-5	1 (7.1%)		2 (13.3%)	
	5-7	0 (0.0%)		1 (6.7%)	
	7-10	1 (7.1%)		6 (40.0%)	
	more than 10 years	3 (21.4%)		6 (40.0%)	
	do not know	1 (7.1%)		0 (0.0%)	

Do you use diabetes medications?	Yes	12 (85.7%)	14 (93.3%)
	No	2 (14.3%)	1 (6.7%)

Table 5-1: Summary of the participants' demographic characteristics

5.1.1.4 Data collection adherence:

Participants recruited for the study were invited to Al-Zulfi General Hospital on June 10th, 2021. During this visit, they were given consent forms and information sheets about the intervention, providing them with an opportunity to ask questions and discuss any concerns related to their participation. Furthermore, baseline data, including measures of HbA1c, blood pressure, BMI, weight, and waist circumference, were collected during this visit. Due to the restrictions imposed by COVID-19, all required measurements and paperwork were completed in a single visit. Participants were then asked to complete two electronic questionnaires: the Diabetes Self-Care Activities (SDSCA) scale and the Self-efficacy Scale for Diabetes. The baseline data collection was successfully completed by all 30 participants, yielding a 100% completion rate. The time taken to complete the questionnaires ranged from 7 to 12 minutes, with no participants reporting difficulties or issues in the completion process.

At the end of the intervention, participants were once again invited to the hospital to gather post-intervention data. This second data collection session was much like the first, where we again measured HbA1c, blood pressure, BMI, weight, and waist circumference. Participants were also asked to complete the initial two questionnaires, with the addition of a Likert-scale Satisfaction Questionnaire for the intervention group only. This additional questionnaire resulted in a slightly longer completion time, ranging from 9 to 15 minutes, due to the inclusion of open-ended questions and certain items requiring justifications or explanations for selected responses. Overall, all participants effectively completed the data collection process, demonstrating successful adherence to our study's data collection procedures.

5.1.1.5 Health coaching intervention:

Eighty-four sessions were undertaken for all participants in the intervention group. Due to the COVID-19 pandemic, the first and last meetings were conducted via video call instead of face-

to-face as planned, while the rest were via telephone. An average of 33.8 minutes with a median of 32.5 and a range of 27-44 minutes were spent for the first sessions. The last sessions took an average of 33.1 minutes across all 11 participants, with a median of 32 and a range of 24-50 minutes. The rest of the four sessions took almost the same time as planned. Participants in the second session spent an average of 15.8 minutes, with a median of 15 and a range of 12-22 minutes. In the third session, participants have undertaken an average of 12.8 minutes of coaching sessions with a median of 11.5 minutes and a range of 10-19 minutes. An average of 13.3 minutes of coaching sessions were taken, with a median of 13.5 minutes and a range of 10-17 minutes. In addition, the average of minutes spent in the fourth session was 12.1, with a median of 12 minutes and a range of 10-17 minutes over 12 weeks.

The intervention started with the first session on 15th June 2021 and ended on 23rd Sep 2021. A total of 1691 minutes of health coaching were conducted during the intervention time. The average time spent per participant was between 17.7 to 25.5 in each session. The total range time of all sessions per patient was 109-153 minutes, with an average of 120.8 (SD= 13.7). See Table 5.2 for more details about the time duration of each session.

Table 5-2: Time spent in each coaching session

Session# / Participant #	1	2	3	4	5	6	TOTAL (minutes)	Mean (minutes)
P01	35	22	12	15	12	37	133	22.2
P06	27	18	17	14	17	25	118	19.7
P09	29	17	10	14	12	24	106	17.7
P10	30	12	14	13	12	30	111	18.5
P03	32	19	19	12	11	33	126	21

P04	27	15	11	15	10	35	113	18.8
P07	33	11	10	14	11	30	109	18.2
P02	35	12	10	11	10	33	111	18.5
P05	31	14	11	12	10	30	108	18
P11	32	18	16	12	15	40	133	22.2
P08	35	13	15	10	12	31	116	19.3
P14	40	13	11	12	10	31	117	19.5
P15	44	22	10	15	12	34	137	22.8
P13	43	15	13	17	15	50	153	25.5
TOTAL (minutes)	473	221	179	186	169	463	1691	
Mean	33.8	15.8	12.8	13.3	12.1	33.1		
Median	32.5	15	11.5	13.5	12	32		
Range	17 (27-44)	11 (12-22)	9 (10-19)	7 (10-17)	7 (10-17)	26 (24-50)		

5.1.1.6 Retention of Participants

Thirty eligible participants consented to participate in the trial and completed the baseline assessment randomly allocated either to the coaching group (n=15) or the control group (n=15). Of these 30 participants, 29 completed all intervention activities and endpoint assessments, resulting in an overall retention rate of approximately 97%. One participant, allocated to the coaching group, withdrew from the study before attending the first session. If considering only those who began the intervention, the retention rate would be 100%, as all 29 participants who attended the first session remained active until the study's endpoint. The progress criteria and feasibility measurement results are summarised in Table 5.3.

Table 5-3: Feasibility Measurements and Predetermined progression criteria

Measure	Definition	Result	Predetermined progression criteria	Notes
Screening rate	Number of screened participants that met the inclusion criteria	38 out of 42 (90%)	> 80% screening rate (this suggests proceeding to the future definitive RCT)	The target for approached participants was adjusted due to the COVID-19 pandemic
Recruitment rate	Number of recruited participants out of the total participants who were eligible during recruited phase	30 out of 38 (79%)	> 70% recruitment rate (this suggests reconsidering before proceeding to the future definitive RCT)	Despite the COVID-19 epidemic, the recruitment rate nearly met the predetermined standard (> 80%)
Retention rate at 3-months	Number of participants who completed the trial out of the total sample	29 out of 30 (97%)	> 83 % retention rate at 3-months (this suggests proceeding to the future definitive RCT)	The retention rate at 3-months was high (all participants who took the first session has completed all the six sessions)
Baseline data collection adherence	Number of participants who completed the assessments at the intervention baseline out of the total study sample	30 out of 30 (100%)		All participants have completed study assessments at the baseline
Intervention adherence (coaching group only)	Number of participants who completed 5 out of six coaching sessions ≥ 84%	6 out of 6 sessions per participant (100%)	>84% of the intervention (≥ 5 out of the 6 coaching sessions) (this suggests proceeding to the future definitive RCT)	
Endpoint data collection adherence	Number of participants who completed the assessments at the intervention endpoint	29 out of 30 participants (96.6%)		Only one participant has withdrawn before the first session

	out of the total study sample

5.1.1.7 Sample size

In the present feasibility study, one of the objectives was to estimate the required sample size for the main trial. The sample size calculation was performed using the SampSize App [179], based on the study's observed effect size of -0.93, a power of 0.8, and an alpha level of 0.05. This calculation indicated a minimum of 20 participants per group would be needed. Although our study achieved approximately 97% retention rate, we expect the retention rate in the main study to be around 80% to 90% (20% dropout), as reported in similar interventions [180]. Therefore, a total of 24 participants in each group would be required to detect a meaningful clinical difference in HbA1c.

When we estimated the sample size using the findings of this study (SD = 2.09 and mean difference = -1.86), the future main trial would need at least 25 participants per group for a power of 0.8 and an alpha level of 0.05, accounting for an estimated 20% dropout. However, given the small sample size of this study and the single setting in which it was conducted, these findings should be used cautiously to estimate the sample size for the future larger RCT [181].

Considering the large observed effect size of -0.93 in this study, it might be more appropriate to estimate the sample size based on the literature for a clinically meaningful mean difference of 0.5% and an SD of 1.4[182 183]. Using a power of 0.8 and an alpha level of 0.05, the future main study would require 125 participants per group. A larger sample size will also enable subgroup analyses to determine if the effect size is greater in specific settings or among certain patient groups.

5.1.1.8 Adherence to the coaching sessions

Out of the 30 participants, 15 were randomly assigned to the coaching group. One participant withdrew before the first session due to family issues (P12). The remaining 14 completed all their coaching sessions, resulting in an adherence rate of 100%, which met the predetermined progression criteria of adhering to ≥ 84%. Half of the participants attended their sessions as initially scheduled. However, for different reasons, health coaches had to reschedule several sessions for seven participants. The number of rescheduled sessions varied between 1 and 2 for each of these participants. Out of 84 sessions, only 11 sessions were rescheduled (13%). The reasons for the rescheduling were home/work/appointment conflicts (n = 6 sessions), travel (n=1 session), illness (n=3 sessions), and being busy (n=1 session). All participants started their coaching sessions at the same time, on 15th June 2021, except four participants who started later on 1st July 2021. Fifteen days of delay occurred for these participants because their coach could not begin at that time for family issues. In addition, the same four participants had another delay between the fourth and fifth sessions due to the coach's college exams. This led them to finish their last session on 23rd Sep 2021. Table 5.4 summarises the coaching sessions tracking schedule.

Table 5-4: Coaching sessions tracking schedule for each participant

Participant #	First session	Second session	Third session	Forth session	Fifth session	Sixth session	comments
P01	6/15/2021	7/1/2021	7/16/2021	8/1/2021	8/17/2021	9/5/2021	
P06	6/15/2021	7/1/2021	7/16/2021	8/1/2021	8/17/2021	9/5/2021	
P09	6/15/2021	7/1/2021	7/16/2021	8/1/2021	8/17/2021	9/5/2021	
P10	6/15/2021	7/1/2021	7/16/2021	8/1/2021	8/17/2021	9/5/2021	
P11	6/15/2021	7/1/2021	7/16/2021	8/1/2021	8/17/2021	9/5/2021	
P03	6/15/2021	7/1/2021	7/16/2021	8/7/2021	8/20/2021	9/7/2021	1 session reschedule (4)
P04	6/15/2021	7/2/2021	7/17/2021	8/6/2021	8/18/2021	9/5/2021	2 sessions reschedule (3,4)

P07	6/15/2021	7/3/2021	7/18/2021	8/2/2021	8/17/2021	9/5/2021	2 sessions reschedule (3,4)
P02	6/15/2021	7/4/2021	7/17/2021	8/1/2021	8/17/2021	9/5/2021	2 sessions reschedule (2,4)
P05	6/15/2021	7/1/2021	7/16/2021	8/4/2021	8/19/2021	9/5/2021	1 session reschedule (4)
P08	7/1/2021	7/17/2021	8/5/2021	8/19/2021	9/14/2021	9/23/2021	1 session reschedule (4)
P13	7/1/2021	7/17/2021	8/3/2021	8/19/2021	9/14/2021	9/23/2021	
P14	7/1/2021	7/17/2021	8/3/2021	8/19/2021	9/14/2021	9/23/2021	
P15	7/1/2021	7/19/2021	8/6/2021	8/20/2021	9/14/2021	9/23/2021	2 sessions reschedule (2,3)

5.1.1.9 Fidelity of the health coaching intervention

The BCTTv1 taxonomy was used to code the active ingredients of health coaching intervention and mapped it to BCW framework [130]. To facilitate this process and link the intervention to the COM-B model, TDF functions and BCTs, a behavioural analysis was conducted to address the pre-identified barriers from the literature review (see Chapter 2&4). As a result, 36 relevant BCTs were selected and mapped to address the behaviour-related barriers. The intervention's target population was those with poorly managed type 2 diabetes. This enabled the coach to define the problem in behavioural terms, as well as the intervention's target behaviours, as advised by BCW advice [101] (see Table 5.5). The four general behaviours targets of the intervention were:

- Decrease carbohydrate intake for each meal
- Use unsaturated fats as possible (avoid saturated fats)
- Engage in exercise for 30 min five days on a weekly basis
- Monitor waist circumference, and maintain it below (80 cm for women and 94 cm for men)

The health coaching intervention used these targets as the benchmarks to track the progress and changes that the study population would make over a three-month period.

Table 5-5: Defined problems in behavioural terms

Target behaviours	**Decrease carbohydrate intake for each meal**	**Use unsaturated fats as possible (avoid saturated fats)**	**Do exercise for 30 min, five days on a weekly basis**	**Monitor waist circumference, maintain it below (80 cm for women and 94 cm for men)**
Who needs to perform the behaviour	Patient with T2DM	Patient with T2DM	Patient with T2DM	Patient with T2DM
What do they need to do differently to achieve desired change	Increase knowledge about diet (understand food types- healthy food-, understand carbohydrate quantity targets) especially carbohydrate types, e.g., rice and dates, etc. Buy food that contain more fiber How to measure carbohydrate quantity Preparing your own meal as possible to have when you are outside house. Avoid eating fast food as possible	Increase knowledge about diet Understand food types in terms of fats included Increase awareness about the difference about saturated unsaturated fats Avoid eating fast food as possible	Increase knowledge about the role of PA and its related impacts in simple language Understand how to do exercise (indoor and outdoor) Understand what the most suitable and enjoyable exercise Have the energy and the required skills to do PA Understand the importance to be constantly active Overcome the fears of injury Understand the risk factors of being physically inactive	Understand the associations between waist circumference and T2DM Understand the recommended target of waist size Understand how to maintain a good size Taking the measurement frequently for comparison
When do they need to do it?	Gradually as much as you can	Use unsaturated fats as much as you can	Gradually as much as you can	Once a month
Where do they need to do it	When you eat anywhere	When you eat anywhere	Anywhere	Anywhere

Target behaviours	**Decrease carbohydrate intake for each meal**	**Use unsaturated fats as possible (avoid saturated fats)**	**Do exercise for 30 min, five days on a weekly basis**	**Monitor waist circumference, maintain it below (80 cm for women and 94 cm for men)**
With whom do they need to do it?	Alone or with people Having social support e.g., family members or friends to stay motivated to change the behaviour	Alone or with people Having social support e.g., family members or friends to stay motivated to change the behaviour	Alone or with people Having social support e.g., family members or friends to stay motivated to change and maintain the behaviour Meeting people at parks to walk together Register in fitness center, if possible, to avoid any environmental restrictions Buy essential PA equipment, if possible, to avoid any environmental restrictions Do the most suitable and enjoyable exercise	As you want

Table modified from (Michie et al., 2014)[101]

In each session, health coaches used a special form to record the BCTs they used with their patients (see Appendix 10). Additional coding was conducted to the audio-recorded coaching session to identify more used BCTs. Tables 5.6,5.7,5.8, and 5.9 below present and map how the intervention links each behaviour target to specific intervention functions and BCTs.

Table 5-6: Behaviour target 1 (Decrease carbohydrate intake for each meal)

Intervention Function	**COM-B**	**Frequently used BCTs**	**How BCT used in context**
Education	Capability- Psychological Motivation- Reflective	*5.1Information about health consequences* *2.2 Feedback on behaviour* *2.3 Self-monitoring of behaviour*	5.1- negative impact of high quantity of carb on body 2.2- inform patients how many calories they have based on consumed food 2.3- ask and help a patient to record their daily carb intake
Training	Motivation - Reflective	*6.1 Demonstration of the behaviour* *4.1 Instruction on how to perform a behaviour* *8.1 Behavioural practice/rehearsal* *8.3 Habit Formation* *8.7 Graded tasks* *10.9 Self-reward*	6.1- show a patient how to read nutrition value when buying any food 4.1- advise a patient hoe how to measure carb when preparing food or consuming it 8.1- practice how to measure carb of different food types 8.3- repeat calculating daily carb intake 8.7- advise a patient to gradually decrease daily carb intake 10.9- advise a patient to set a self-reward (valued objects) when achieving short- or long-term goals

Intervention Function	COM-B	Frequently used BCTs	How BCT used in context
Enablement	Capability - Psychological Opportunity - Physical	*1.3 Goal setting (outcome)* *1.1 Goal setting (Behaviour)* *1.5 Review behaviour goal (s)* *1.7 Review outcome goal (s)* *3.1 Social support (unspecified)* *1.4 Action planning* *1.2 Problem-solving* *9.2 Pros and cons* *9.3 Comparative imagining of future outcomes* *1.9 Commitment* *5.5 Anticipated regret* *15.2 Mental rehearsal of successful performance* *12.3Avoidance/reducing exposure to cues for the behaviour* *13.1 Identification of self as role model*	1.3- set a goal of daily carb intake 1.1- advise a patient to use spoons instead of hand when eating (e.g., rice) 1.5- re-setting the same goal to be reasonable to achieve (reduce carb intake instead of stop eating it) 1.7- re-setting the daily carb intake e.g., number of dates consumed per day 3.1- encourage a patient to have support from friend or family to reduce the daily carb intake e.g., educate a patient about carb sources 1.4- encourage a patient to have weekly plan of having different source of carb 1.2- advise a patient to have alternative and potential barriers and prepare plan to overcome 9.2- Advise a patient to compare between pros and cons of reducing carb intake

Intervention Function	COM-B	Frequently used BCTs	How BCT used in context
			9.3- advise a patient to imagine the impact of continuing with high carb intake vs low cab intake 9.1- a patient affirm of staying committed to achieve intended goals 5.5- encourage a patient to imagine the complications and consequences if the quantity of daily carb stays high 15.2 Advice to imagine eating and enjoying alternative health food with a low carb like a salad at work or snack and (staying saturated with controlled blood sugar) 12.3- encourage a patient to avoid going to party or friend when hungry e.g., eat snack to make you feel full 13.1- encourage a patient to be a good example for their family or friends

Intervention Function	COM-B	Frequently used BCTs	How BCT used in context
Environmental restructuring	Opportunity - Physical	*12.1 Restructuring the physical environment* *12.5 Adding objects to the environment* *12.2 Restructuring the social environment* *7.1 Prompts/Cues*	12.1- Advise to have healthy snacks (e.g., high protein) between meals to decrease the feeling of hunger 12.5- advise a patient to put healthy snakes e.g., fruits in observable place like on the table of living room 12.2 encourage a patient to eat at home before going out with friends who heavily relay on fast food 7.1- put a note paper with low carb food at the kitchen (reminder)
Modelling	Motivation - Reflective	*6.1 Demonstration of the behaviour*	6.1- Provide others' positive experiences of people (shift consumption from high carb food intake to enjoy low carb intake for inspiration purpose and imitation)
Persuasion	Motivation - Reflective	*15.1 Verbal persuasion about capability* *15.4 Self-talk* *13.2 Framing/reframing* *15.3 Focus on past success*	15.1 telling patents that they can decrease daily carb intake and enjoy the new experience 15.4- prompt patients to tell

Intervention Function	COM-B	Frequently used BCTs	How BCT used in context
		5.3 Information about social and *environmental* *consequences* *5.6 Information about emotional consequences* *6.3 Information about others' approval* *2.7. Feedback on outcome(s) of behaviour* *9.1Credible source*	themselves that there are many alternative food types with low carb they can enjoy eating 13.2- encourage a patient to see the carb decrease as a way of feeling saturated with food with high protein or fibre intake rather than decreasing blood Sugrue 15.3- encourage patients to speak about previous successful attempts where they could decrease their daily carb intake 5.3- social and finical consequences of not taking action to control the quantity of carb 5.6- ability to decrease daily carb intake will give you a feeling of confidence toward controlling blood sugar and happiness 6.3- tell a patient that other people approve to decrease daily carb intake e.g., number of dates 2.7- inform a patient how

Intervention Function	COM-B	Frequently used BCTs	How BCT used in context
			reducing carb intake affect level of blood sugar 9.1- share videos from high-status physicians to emphasise the significance of the link between decreasing daily carb intake and blood sugar control

Table 5-7: Behaviour target 2 (Use unsaturated fats where possible ((avoid saturated fats))

Intervention Function	COM-B	Frequently used BCTs	How BCT used in context
Education	Capability- Psychological Motivation- Reflective	*5.1Information about health consequences*	5.1- negative impact of saturated fats on health condition
Training	Motivation - Reflective	*6.1 Demonstration of the behaviour* *8.3 Habit Formation* *8.7 Graded tasks*	6.1- encourage a patient how to read nutrition value (fat types) when buying any food 8.3- eat only unsaturated fat food until it becomes a habit 8.7- advise patients to gradually shifting their usage of fat to unsaturated fat
Enablement	Capability - Psychological Opportunity - Physical	*1.1 Goal setting (Behaviour)* *3.1 Social support (unspecified)* *1.2 Problem-solving*	1.1- patients only use unsaturated fat 3.1- encourage patients to tell friends or

Intervention Function	COM-B	Frequently used BCTs	How BCT used in context
		9.2 Pros and cons *9.3 Comparative imagining of future outcomes* *1.9 Commitment* *12.3Avoidance/reducing exposure to cues for the behaviour* *13.1 Identification of self as role model*	families that they only use unsaturated fat 1.2- advise a patient to have alternative and potential barriers and prepare plan to overcome 9.2- Advise a patient to think and compare between pros and cons of using unsaturated fat 9.3- advise a patient to imagine the impact of consuming saturated fat food vs unsaturated fat food 9.1- a patient affirm of staying committed to achieve intended goals 12.3- encourage a patient to avoid using saturated fat or trans-fat when going to party or with friend 13.1- encourage a patient to be a good example for their family or friends
Environmental restructuring	Opportunity - Physical	*12.1 Restructuring the physical environment* *12.5 Adding objects to the environment*	12.1- Advise to buy and use only unsaturated fat for cooking 12.5- advise to put unsaturated

Intervention Function	COM-B	Frequently used BCTs	How BCT used in context
		12.2 Restructuring the social environment	fat on kitchen table 12.2 encourage patients to advise their friends or families the benefit of replacing saturated fat with unsaturated
Modelling	Motivation - Reflective	none	none
Persuasion	Motivation - Reflective	*15.1 Verbal persuasion about capability* *15.3 Focus on past success* *5.3 Information about social and* *environmental consequences* *6.3 Information about others' approval* *2.7. Feedback on outcome(s) of behaviour*	15.1 telling patents that they can replace the use of saturated to unsaturated fat and enjoy the new experience 15.3- encourage patients to remember and speak about previous successful attempts with unsaturated-diet 5.3- social and finical consequences of not taking action to replace saturated with unsaturated fat 6.3- tell a patient that other people approve to replace saturated fat by unsaturated fat (e.g., olive oil) 2.7- inform a patient how replacing or reducing unsaturated fat

Intervention Function	COM-B	Frequently used BCTs	How BCT used in context
			would affect health condition

Table 5-8: Behaviour target 3 (Do exercise for 30 min, five days on a weekly basis)

Intervention Function	COM-B	Frequently used BCTs	How BCT used in context
Education	Capability- Psychological Motivation- Reflective	*5.1Information about health consequences* *7.1 Prompts/Cues* *2.3 Self-monitoring of behaviour*	5.1- negative impact of sedentary behaviour (being physical inactive) 7.1- advise patients to use steps tracker to check their activity every day (apps or sport watches) 2.3- ask and help a patient to record their daily activity
Training	Motivation - Reflective	*4.1 Instruction on how to perform a behaviour* *8.3 Habit Formation* *8.7 Graded tasks* *10.9 Self-reward*	4.1- advise a patient how to do specific type of exercise 8.3- repeat daily exercise at your preferred time 8.7- advise a patient to gradually increase daily exercise time 10.9- advise a patient to set a self-reward (valued objects) when achieving short- or long-term goals
Enablement	Capability - Psychological Opportunity - Physical	*1.3 Goal setting (outcome)* *1.1 Goal setting (Behaviour)* *1.5 Review behaviour goal (s)* *1.7 Review outcome goal (s)* *3.1 Social support (unspecified)* *1.4 Action planning* *1.2 Problem-solving*	1.3- set a goal of daily steps or exercise time 1.1- advise a patient to limit car usage (walk instead) 1.5- re-setting the same goal to be reasonable to achieve (reduce carb intake instead of stop eating it) 1.7- re-setting the daily carb intake e.g., number of dates consumed per day 3.1- encourage a patient to have

Intervention Function	COM-B	Frequently used BCTs	How BCT used in context
		9.2 Pros and cons *9.3 Comparative imagining of future outcomes* *1.9 Commitment* *5.5 Anticipated regret* *15.2 Mental rehearsal of successful performance* *13.1 Identification of self as role model*	support from friend or family (e.g., join walk club, conduct a meeting while walking or doing exercise 1.4- encourage a patient to have weekly plan to complete weekly steps e.g., 150 minutes 1.2- advise a patient to ahead prepared for any barriers to overcome 9.2- Advise a patient to compare between pros and cons of being active 9.3- advise a patient to imagine the impact of adapting new behaviour and its impacts on blood Sugrue levels 9.1- a patient affirm of staying committed to achieve intended goals 5.5- encourage a patient to imagine the complications and consequences of being inactive 15.2 Advice to imagine the happiness of being active 13.1- encourage a patient to be a good example for their family or friends (e.g., walk to mosque instead of using car)
Environmental restructuring	Opportunity - Physical	*12.1 Restructuring the physical environment* *12.5 Adding objects to the environment* *12.2 Restructuring the social environment*	12.1- Advise a patient to do resistance exercise while watching T.V 12.5- Advise to have exercise equipment in observable place e.g., living room

Intervention Function	COM-B	Frequently used BCTs	How BCT used in context
			12.2 encourage a patient to join social exercise events or clubs
Modelling	Motivation - Reflective	*6.1 Demonstration of the behaviour*	6.1- Provide others' positive experiences of people adapted daily exercise in their lifestyle
Persuasion	Motivation - Reflective	*15.1 Verbal persuasion about capability* *13.2 Framing/reframing* *15.3 Focus on past success* *5.3 Information about social and environmental consequences* *2.7. Feedback on outcome(s) of behaviour* *9.1Credible source* *5.6 Information about emotional consequences* *6.3 Information about others' approval*	15.1 telling patients that they can include 30 minutes of exercise daily 13.2- encourage a patient to see their daily exercise as an opportunity to finish some work e.g., calls or listen to podcasts or any thing 15.3- encourage patients to speak about previous successful attempts 5.3- social and finical consequences of not taking action and being active 2.7- inform a patient how exercise affect level of blood sugar 9.1- share videos from high-status professionals emphasise the significance being physically active 5.6- ability to do daily exercise will give you a feeling of confidence toward controlling blood sugar and happiness 6.3- tell a patient that other people approve to do daily exercise e.g., 3000-7000 steps daily

Table 5-9: Behaviour target 4 (Monitor waist circumference, maintain it below (80 cm for women and 94 cm for men)

Intervention Function	**COM-B**	**Frequently used BCTs**	**How BCT used in context**
Education	Capability- Psychological Motivation- Reflective	*5.1Information about health consequences*	5.1- negative impact of being overweight and waist circumference above the normal
Training	Motivation - Reflective	*4.1 Instruction on how to perform a behaviour*	4.1- instruct a patient on how to measure waist circumference
Enablement	Capability - Psychological Opportunity - Physical	*1.3 Goal setting (outcome)* *1.1 Goal setting (Behaviour)* *9.3 Comparative imagining of future outcomes*	1.3- set a goal to reduce waist circumference 1.1- set a goal to regularly measure waist circumference 9.3- advise a patient to imagine the impact of neglecting to measure and maintain normal waist circumference
Environmental restructuring	Opportunity - Physical	None	None
Modelling	Motivation - Reflective	None	None
Persuasion	Motivation - Reflective	*15.1 Verbal persuasion about capability* *2.7. Feedback on outcome(s) of behaviour*	15.1 telling patients that they can decrease and maintain normal waist circumference 2.7- inform patients how regularly measuring waist circumference would encourage

Intervention Function	COM-B	Frequently used BCTs	How BCT used in context
			them to maintain a normal size

In total, 36 BCTs were used in 84 coaching sessions; the total number of BCTs reported across all coaching sessions combined was 773, with an average of 21.4 (SD=8.8). The following five BCTs were added and used which had not originally been in the intervention BCTs list; *2.7 Feedback on outcome(s) of behaviour, 13.1 Identification of self as role model, 12.3Avoidance/reducing exposure to cues for the behaviour, 6.3 Information about others' approval, 5.6 Information about emotional consequences.* The most frequently used technique was *1.3 Goal setting (outcome),* which was used 43 times with three behaviour targets; decrease carbohydrate intake for each meal, exercise for 30 min five days weekly*, and* monitor waist circumference. This technique was mainly used in the first and third sessions, where participants had the opportunity to modify their behaviour goals. *1.3 Goal setting (outcome)* and *1.7 Review outcome goal (s)* was the second most frequent technique, which allowed patients to review and reset their outcome goals. The least used technique in the intervention was *15.4 Self-talk,* which was used only six times. Table 5.10 presents BCTs, their behaviour targets, and the techniques' frequency.

Table 5-10: BCTs used in the interventions

	BCT	Behaviour target (s)	Frequency Used
1.	*1.1 Goal setting (Behaviour)*	• Decrease carbohydrate intake for each meal • Use unsaturated fats as possible (avoid saturated fats) • Do exercise for 30 min, five days on a weekly basis • Monitor waist circumference	43
2.	*1.2 Problem-solving*	• Decrease carbohydrate intake for each meal • Use unsaturated fats as possible (avoid saturated fats)	28

	BCT	Behaviour target (s)	Frequency Used
		• Do exercise for 30 min, five days on a weekly basis	
3.	*1.3 Goal setting (outcome)*	• Decrease carbohydrate intake for each meal • Do exercise for 30 min, five days on a weekly basis • Monitor waist circumference	34
4.	*1.4 Action planning*	• Decrease carbohydrate intake for each meal • Do exercise for 30 min, five days on a weekly basis	27
5.	*1.5 Review behaviour goal (s)*	• Decrease carbohydrate intake for each meal • Do exercise for 30 min, five days on a weekly basis	34
6.	*1.7 Review outcome goal (s)*	• Decrease carbohydrate intake for each meal • Do exercise for 30 min, five days on a weekly basis	39
7.	*1.9 Commitment*	• Decrease carbohydrate intake for each meal • Use unsaturated fats as possible (avoid saturated fats) • Do exercise for 30 min, five days on a weekly basis	18
8.	*2.2 Feedback on behaviour*	• Decrease carbohydrate intake for each meal	17
9.	*2.3 Self-monitoring of behaviour*	• Decrease carbohydrate intake for each meal • Do exercise for 30 min, five days on a weekly basis	15
10.	*2.7. Feedback on outcome(s) of behaviour*	• Decrease carbohydrate intake for each meal • Use unsaturated fats as possible (avoid saturated fats) • Do exercise for 30 min, five days on a weekly basis • Monitor waist circumference	22
11.	*3.1 Social support (unspecified)*	• Decrease carbohydrate intake for each meal • Use unsaturated fats as possible (avoid saturated fats) • Do exercise for 30 min, five days on a weekly basis	29
12.	*4.1 Instruction on how to perform a behaviour*	• Decrease carbohydrate intake for each meal	14

	BCT	Behaviour target (s)	Frequency Used
		• Do exercise for 30 min, five days on a weekly basis • Monitor waist circumference	
13.	*5.1Information about health consequences*	• Decrease carbohydrate intake for each meal • Use unsaturated fats as possible (avoid saturated fats) • Do exercise for 30 min, five days on a weekly basis • Monitor waist circumference	27
14.	*5.3 Information about social and environmental consequences*	• Decrease carbohydrate intake for each meal • Use unsaturated fats as possible (avoid saturated fats) • Do exercise for 30 min, five days on a weekly basis	19
15.	*5.5 Anticipated regret*	• Decrease carbohydrate intake for each meal • Do exercise for 30 min, five days on a weekly basis	15
16.	*5.6 Information about emotional consequences*	• Decrease carbohydrate intake for each meal • Do exercise for 30 min, five days on a weekly basis	11
17.	*6.1 Demonstration of the behaviour*	• Decrease carbohydrate intake for each meal • Use unsaturated fats as possible (avoid saturated fats) • Do exercise for 30 min, five days on a weekly basis	14
18.	*6.3 Information about others' approval*	• Decrease carbohydrate intake for each meal • Use unsaturated fats as possible (avoid saturated fats) • Do exercise for 30 min, five days on a weekly basis	14
19.	*8.1 Behavioural practice/rehearsal*	• Decrease carbohydrate intake for each meal	22
20.	*8.3 Habit Formation*	• Decrease carbohydrate intake for each meal • Use unsaturated fats as possible (avoid saturated fats) • Do exercise for 30 min, five days on a weekly basis	28
21.	*8.7 Graded tasks*	• Decrease carbohydrate intake for each meal	31

	BCT	Behaviour target (s)	Frequency Used
		• Use unsaturated fats as possible (avoid saturated fats) • Do exercise for 30 min, five days on a weekly basis	
22.	*9.1Credible source*	• Decrease carbohydrate intake for each meal • Do exercise for 30 min, five days on a weekly basis	17
23.	*9.2 Pros and cons*	• Decrease carbohydrate intake for each meal • Use unsaturated fats as possible (avoid saturated fats) • Do exercise for 30 min, five days on a weekly basis	15
24.	*7.1 Prompts/Cues*	• Decrease carbohydrate intake for each meal • Do exercise for 30 min, five days on a weekly basis	9
25.	*9.3 Comparative imagining of future outcomes*	• Decrease carbohydrate intake for each meal • Use unsaturated fats as possible (avoid saturated fats) • Do exercise for 30 min, five days on a weekly basis • Monitor waist circumference	27
26.	*10.9 Self-reward*	• Decrease carbohydrate intake for each meal • Do exercise for 30 min, five days on a weekly basis	8
27.	*12.1 Restructuring the physical environment*	• Decrease carbohydrate intake for each meal • Use unsaturated fats as possible (avoid saturated fats) • Do exercise for 30 min, five days on a weekly basis	26
28.	*12.2 Restructuring the social environment*	• Decrease carbohydrate intake for each meal • Use unsaturated fats as possible (avoid saturated fats) • Do exercise for 30 min, five days on a weekly basis	28
29.	*12.3Avoidance/reducing exposure to cues for the behaviour*	• Decrease carbohydrate intake for each meal • Use unsaturated fats as possible (avoid saturated fats)	18

	BCT	Behaviour target (s)	Frequency Used
30.	*12.5 Adding objects to the environment*	• Decrease carbohydrate intake for each meal • Use unsaturated fats as possible (avoid saturated fats) • Do exercise for 30 min, five days on a weekly basis	16
31.	*13.1 Identification of self as role model*	• Decrease carbohydrate intake for each meal • Use unsaturated fats as possible (avoid saturated fats) • Do exercise for 30 min, five days on a weekly basis	14
32.	*13.2 Framing/reframing*	• Decrease carbohydrate intake for each meal • Do exercise for 30 min, five days on a weekly basis	16
33.	*15.1 Verbal persuasion about capability*	• Decrease carbohydrate intake for each meal • Use unsaturated fats as possible (avoid saturated fats) • Do exercise for 30 min, five days on a weekly basis • Monitor waist circumference	30
34.	*15.2 Mental rehearsal of successful performance*	• Decrease carbohydrate intake for each meal • Do exercise for 30 min, five days on a weekly basis	17
35.	*15.3 Focus on past success*	• Decrease carbohydrate intake for each meal • Use unsaturated fats as possible (avoid saturated fats) • Do exercise for 30 min, five days on a weekly basis	24
36.	*15.4 Self-talk*	• Decrease carbohydrate intake for each meal	7

5.1.2 Acceptability of the intervention

The acceptability of the intervention was assessed through a questionnaire (Likert-scale Satisfaction Questionnaire, 14 items) for the intervention group (n = 14). We used descriptive statistics, specifically the mean and standard deviation (SD), to analyze and present the data collected from survey questions that used Likert-scale responses. These results can be found in

Tables 5.11 and 5.12. Participants' responses to open-ended items were coded and classified into main themes using content analysis.

Table 5.11 presents the participant ratings of health coaching in the intervention group, utilising a 10-point Likert scale. Notably, the highest ratings were observed for creating a personal vision of wellness, achieving a mean score of 9.21 (SD = 1.36). This implies that health coaching may be effective in assisting participants in envisioning their wellness goals. Conversely, the lowest rating was attributed to utilising problem-solving skills, receiving a mean score of 8.57 (SD = 1.39). As part of our study, we evaluated the Likert-scale Satisfaction Questionnaire and found that the 8 items had a high level of internal consistency with a Cronbach's alpha of 0.88. Tables 5.11 and 5.12 provide further details about participants' responses to each question.

Table 5-11: Participant Ratings of Health Coaching on a 10-Point Likert Scale (intervention group only)

Question	N	Mean [a]	Std. Deviation	Range
To what extent did participation in health coaching:				
1. Changed you/your behaviour	14	8.14	2.38	3-10
2. Helped create a personal vision of wellness	14	9.21	1.36	6-10
3. Increase your confidence to take steps to greater wellness	14	9.21	1.36	6-10
4. Increase your motivation to take steps to greater wellness	14	9.14	1.35	6-10
5. Increase your use of goal setting skills	14	9.21	.89	7-10
6. Increase your use of problem-solving skills	14	8.57	1.39	5-10
7. Help get you back on track after running into barriers	14	9.07	1.07	7-10
8. Help you achieve greater wellness	14	9.14	1.09	7-10

[a] Scale of 0 to 10, with 0 (not at all) to 10 (very much)

Participants were asked three "Yes" or "No" questions, and they all replied "Yes" when asked whether they expected to continue making improvements (n=14, 100%). The majority (n=13, 92.9%) responded with "Yes" the intervention met their expectations. All 14 participants who were asked whether they would recommend the intervention to others responded with a positive "yes". The rest of the questions (n=3) were open-ended: "What was most helpful about participating in wellness coaching?" "What was least helpful about participating in wellness coaching?" "What about your relationship with the coach was helpful to you, if anything? Please explain:" These questions were analysed and included in the thematic analysis section.

Table 5-12: Frequency and percent of each participant's response

To what extent did participation in health coaching:		Frequency	Percent
1. Changed you/your behaviour	A little bit	1	7.1
	Somewhat	2	14.3
	Quite a bit	3	21.4
	Very Much	8	57.1
2. Helped create a personal vision of wellness	Somewhat	1	7.1
	Quite a bit	3	21.4
	Very Much	10	71.4
3. Increase your confidence to take steps to greater wellness	Somewhat	1	7.1
	Quite a bit	3	21.4
	Very Much	10	71.4
4. Increase your motivation to take steps to greater wellness	Somewhat	1	7.1
	Quite a bit	3	21.4
	Very Much	10	71.4
5. Increase your use of goal setting skill	Quite a bit	2	14.3
	Very Much	12	85.7
6. Increase your use of problem-solving skills	Somewhat	1	7.1
	Quite a bit	5	35.7

	Very Much	8	57.1
7. Help get you back on track after running into barriers	Quite a bit	5	35.7
	Very Much	9	64.3
8. Help you achieve greater wellness	Quite a bit	3	21.4
	Very Much	11	78.6

5.1.2.1 Preliminary effects of the intervention

The preliminary intervention effects consist of primary and secondary outcomes. HbA1c was the primary outcome, while the intervention's secondary outcomes included Blood pressure, BMI, Waist circumference, Weight, Patients' self-efficacy, and Diabetes self-management. Each one of these outcomes is discussed in more detail below.

5.1.2.1.1 Glycosylated haemoglobin (HbA1c)

A linear regression model was used to evaluate the efficacy of a health coaching intervention aimed at reducing participants' HbA1c levels between the two groups adjusted for baseline HbA1c levels. The overall average HbA1c level among all participants decreased from 8.92% (SD= 2.09) at baseline to 8.14% (SD= 1.79) at the end of the study. The mean difference in HbA1c levels between pre-and post-intervention was 0.8 for all participants. The estimated mean difference in post-intervention HbA1c levels between the two groups after adjusting for the baseline HbA1c level from the regression analysis model is -1.86 (95% CI: -2.71 to -1.01, P<0.001). Participants in the intervention group with elevated baseline HbA1c levels (≥7%, n=14) achieved a significant reduction in HbA1c levels of 1.84% over a period of three months, from 9.1% (SD= 2.50) at baseline to 7.2% (SD= 1.38) post-intervention. Conversely, the HbA1c levels in the control group increased from 8.7% (SD= 1.69) at baseline to 8.9% (SD= 1.81) by the end of the study. Tables 5.13 and 5.14 provide further details. Figure 5.2 shows HbA1c level changes for each participant in each group from the study baseline to the endpoint.

Table 5-13: HbA1c means and SDs for both groups at the study baseline and endpoint

	Group	N	Mean	Std. Deviation
A1c level at the study baseline	Intervention Group	14	9.12	2.50
	Control Group	15	8.73	1.69
A1c level at the study endpoint	Intervention Group	14	7.29	1.38
	Control Group	15	8.93	1.81

Table 5-14: HbA1c outcome difference, taking into account the baseline value

Endpoint HbA1c	*Mean difference*	*Std. err.*	*t*	*P>t*	*[95% CI]*	
*Group**	-1.864	.414	-4.50	<0.001	-2.716065	-1.012862
Baseline HbA1c	.566			<0.001	.3601448	.7732833

*(Group = Intervention mean – Control mean)

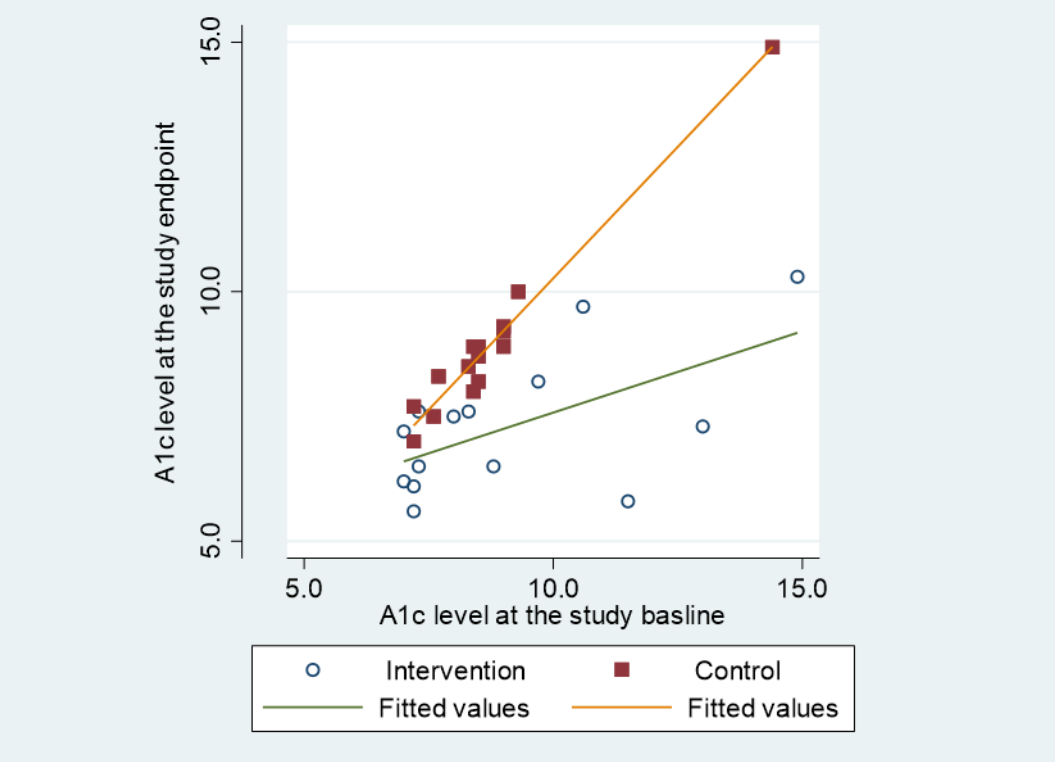

Figure 5-2:HbA1c level changes for each participant in each group from the study baseline to the endpoint

5.1.2.2 Secondary outcomes

5.1.2.2.1 Mean Arterial Pressure (MAP)

The mean differences were computed using Mean Arterial Pressure (MAP), which represents the average arterial pressure over a single cardiac cycle that includes both systole and diastole [184]. The average MAP for all participants (n=29) was 89.1 mmHg (SD= 12.64) at baseline and 91.4 mmHg (SD= 11.1) at the end of the study. The estimated mean difference in post-intervention MAP scores between the two groups after adjusting for the baseline MAP level is -.68 (95% CI: 7.46 to 6.09, p=0.83). A detailed explanation of these findings can be found in Tables 5.15 and 5.16. The variability of MAP values of participants in each group relative to the fitted line is presented in Figure 5.3.

5.1.2.2.2 Weight

The weight difference between the two groups was assessed by comparing their means using a linear regression model. A slight reduction in the average weight of all participants (n=29) was observed, decreasing from 82.3 kg (SD= 12.22) at baseline to 80.9 kg (SD= 11.56) at the endpoint. Although the intervention group (n=14) had a decrease in weight of 2.79 kg, the difference was not statistically significant, with a mean difference of -2.58 (95% CI: -5.25 to .082, P= 0.06). Tables 5.15 and 5.16 and Figure 5.4 provide further details.

5.1.2.2.3 BMI

The average BMI for all participants (n=29) was similar at baseline (30.6, SD= 4.95) and endpoint (30.15, SD= 4.84). However, the intervention group (n=14) showed a greater change from baseline (30.39, SD= 4.57) to 29.39 (SD= 4.33) after the intervention, compared to the control group (from 30.87, SD= 5.43 to 30.86, SD= 5.31). The post-intervention mean difference between the two groups was significant, with -1.02 (95% CI: -2.01 to -.041, P=0.04). See Tables 5.15 and 5.16, and Figure 5.5 for further details.

5.1.2.2.4 Waist Circumference

The average waist circumference for all participants (n=29) decreased from 107.9 cm ± 11.83 at baseline to 104.56 cm (SD= 11.30) at the endpoint. The intervention group (n=14) showed a larger reduction from 106.6 cm (SD= 13.60) at baseline to 102.21 cm (SD= 12.55) after the intervention. Conversely, the control group (n=15) had a slight increase in waist circumference by 0.09 cm at the endpoint. The estimated mean difference in post-intervention waist circumference scores between the two groups after adjusting for the baseline waist circumference scores is -6.89 (95% CI: -10.17 to -3.61, P<0.001). Further details are provided in Tables 5.15, Table 5.16, and Figure 5.6.

Table 5-15: Groups means and SDs at study baseline and endpoint

Variable	Group	N	Mean	Std. Deviation
Mean Arterial Pressure at the study baseline	Intervention Group	14	91.76	13.562
	Control Group	15	86.73	11.665
Mean Arterial Pressure at the study endpoint	Intervention Group	14	92.57	9.118
	Control Group	15	90.33	12.911
Height (cm) at the study baseline	Intervention Group	14	166	7.24
Height (cm) at the study baseline	Control Group	15	162.5	7.59
Weight in Kg at the study baseline	Intervention Group	14	83.500	11.9791
	Control Group	15	81.213	12.7646
Weight in Kg at the study endpoint	Intervention Group	14	80.707	10.8012
	Control Group	15	81.213	12.6052
BMI at the study baseline	Intervention Group	14	30.3933	4.57832
	Control Group	15	30.8720	5.43983
BMI at the study endpoint	Intervention Group	14	29.3927	4.33016
	Control Group	15	30.8632	5.31890
Waist Circumference (cm) at the study baseline	Intervention Group	14	109.357	13.6077
	Control Group	15	106.667	10.2289

Waist Circumference (cm) at the study endpoint	Intervention Group	14	102.214	12.5587
	Control Group	15	106.760	9.9164

Table 5-16: Secondary outcomes mean differences, taking into account the baseline value

Endpoint MAP	*Mean difference*	*Std. err.*	*t*	*P>t*	*[95% CI]*	
*Group**	-.683	3.298	-0.21	0.837	-7.463123	6.09647
Baseline MAP	.580	.132	4.38	<0.001	.3083653	.8535638
Endpoint Weight	Mean difference	Std. err.	t	P>t	[95% CI]	
Group	-2.584	1.297	-1.99	0.057	-5.252461	.0825133
Baseline Weight	.909	.0539	16.84	<0.001	.7981218	1.020056
Endpoint BMI	Mean difference	Std. err.	t	P>t	[95% CI]	
Group	-1.024	.477	-2.14	0.042	-2.006754	-.0416741
Baseline BMI	.932	.049	19.02	<0.001	.8315092	1.033048
Endpoint WC	Mean difference	Std. err.	t	P>t	[95% CI]	
Group	-6.895	1.597	-4.32	<0.001	-10.17924	-3.611259
Baseline WC	.873	.068	12.72	<0.001	.7322131	1.014345

*(Group = Intervention mean – Control mean)

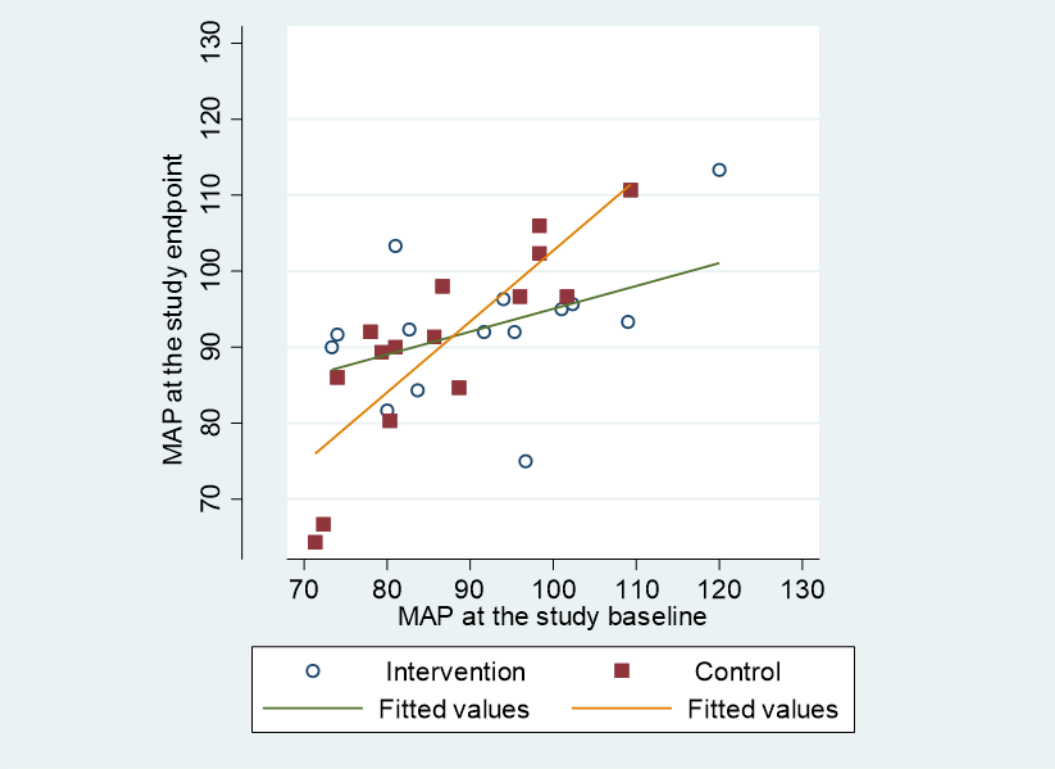

Figure 5-3: MAP changes for each participant in each group from the study baseline to the endpoint

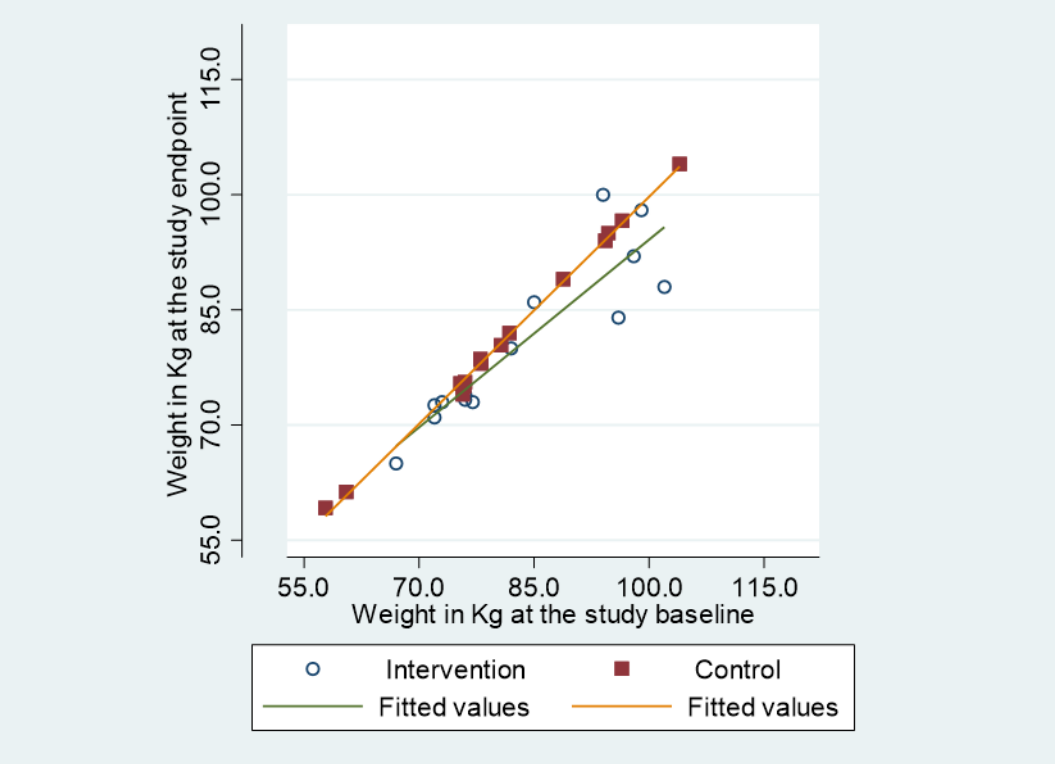

Figure 5-4: Weight changes for each participant in each group from the study baseline to the endpoint

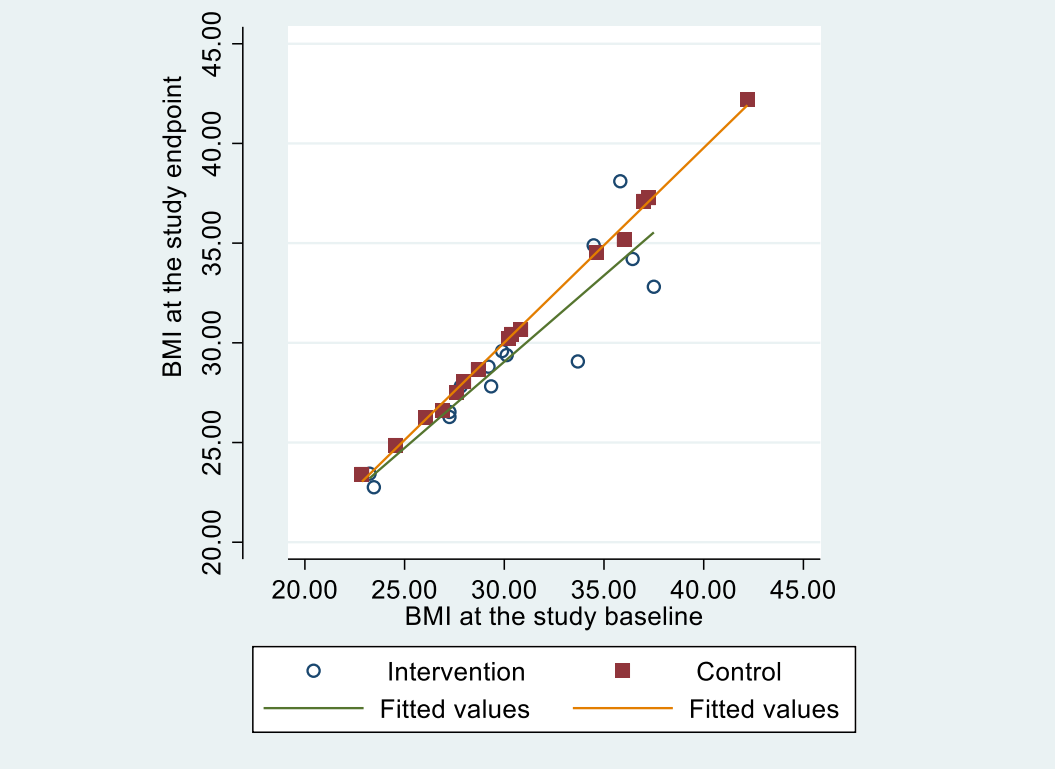

Figure 5-5: BMI changes for each participant in each group from the study baseline to the endpoint

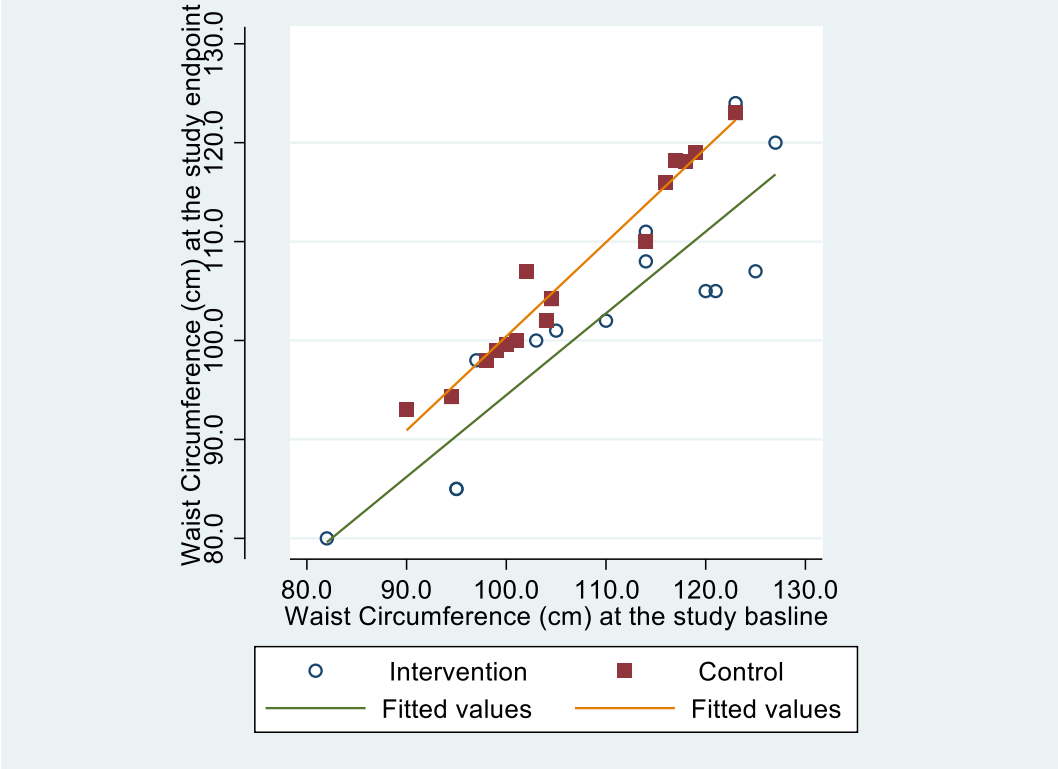

Figure 5-6: Waist circumference changes for each participant in each group from the study baseline to the endpoint

5.1.2.2.5 Patients' self-efficacy questionnaire

Overall, participants' responses to each of the eight questions were higher at the study endpoint, ranging from 1 to 10 (see Appendix 11). Comparison between the two groups varied, with an overall higher confidence rate among participants in the intervention group. Both the intervention and control group had an increased average in participants' responses to the first question from 5.36 ± 3.29 at baseline to 7.21 ± 2.08 for the intervention group versus from 4.60 ± 1.80 to 6.73 ± 1.75 (see Tables 5.17 & 5.18). The mean differences in participants' confidence improved by 2.78 for the intervention group compared to 2.07 for the control group. When participants were asked to rate their confidence toward appropriate food to eat when they are hungry, the mean responses of the intervention and control group were 6.07 ± 3.17 and 5.53 ± 1.685 at baseline compared to 8.21 ± 2.08 and 7.20 ± 1.52 at the endpoint. The improvement of participants' confidence in doing 15 to 30 minutes exercise, 4 to 5 times a week was higher

in the intervention group, with a mean difference of 2.64 (6.50 ± 3.63 to 9.14 ± 1.994), compared to the control group with an improvement of 1.87 in confidence (5.00 ± 2.72 to 6.87 ± 2.10). The difference between the two groups was statistically significant (P = .006, 59 % CI .713 to 3.839). When participants were asked about the extent to which they feel they can control their condition, participants in the intervention group had a larger improvement with an increase of 2.93 (5.93 ± 3.12 to 8.86 ± 2.03), compared to an increase of 0.8 (5.47 ± 2.44 to 6.27 ± 2.549) in the control group. The difference was statistically significant (P = .006, 59% CI 0.82 to 4.35). The reliability of this 8-item questionnaire within our study context was supported by a Cronbach's alpha for internal consistency of 0.79, denoting acceptable reliability.

Table 5-17: Average participants' responses for both groups at baseline

Statistics

		How confident do you feel that you can eat your meals every 4 to 5 hours every day, including breakfast every day? (At the baseline)	How confident do you feel that you can follow your diet when you have to prepare or share food with other people who do not have diabetes? (At the baseline)	How confident do you feel that you can choose the appropriate foods to eat when you are hungry (for example, snacks)? (At the baseline)	How confident do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week? (At the baseline)	How confident do you feel that you can do something to prevent your blood sugar level from dropping when you exercise? (At the baseline)	How confident do you feel that you know what to do when your blood sugar level goes higher or lower than it should be? (At the baseline)	How confident do you feel that you can judge when the changes in your illness mean you should visit the doctor? (At the baseline)	How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do? (At the baseline)
N	Valid	29	29	29	29	29	29	29	29
	Missing	0	0	0	0	0	0	0	0
Mean		4.97	5.21	5.79	5.72	5.76	5.48	6.41	5.69
Std. Deviation		2.612	2.920	2.484	3.228	2.773	2.339	2.457	2.753
Minimum		1	1	1	1	1	1	1	1
Maximum		10	10	10	10	10	10	10	10

Table 5-18: Average participants' responses for both groups at the endpoint

Statistics

		How confident do you feel that you can eat your meals every 4 to 5 hours every day, including breakfast every day? (At endpoint)	How confident do you feel that you can follow your diet when you have to prepare or share food with other people who do not have diabetes? (At endpoint)	How confident do you feel that you can choose the appropriate foods to eat when you are hungry (for example, snacks)? (At endpoint)	How confident do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week? (At endpoint)	How confident do you feel that you can do something to prevent your blood sugar level from dropping when you exercise? (At endpoint)	How confident do you feel that you know what to do when your blood sugar level goes higher or lower than it should be? (At endpoint)	How confident do you feel that you can judge when the changes in your illness mean you should visit the doctor? (At endpoint)	How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do? (At endpoint)
N	Valid	29	29	29	29	29	29	29	29
	Missing	0	0	0	0	0	0	0	0
Mean		6.97	7.62	7.69	7.97	7.14	7.24	7.72	7.52
Std. Deviation		1.899	2.111	1.854	2.322	2.532	2.198	2.297	2.627
Minimum		3	2	4	2	1	3	3	1
Maximum		10	10	10	10	10	10	10	10

5.1.2.2.6 Diabetes Self-Care Activity

The study examined the effects of coaching on participants' self-care practices using the SDSCA scale. Both the intervention and control groups showed improvement in their responses to the seven questions from the start of the study to the end (see Appendix 12). The intervention group demonstrated significant progress in their adherence to the recommended eating plan, with an average of 4.86 days per week compared to the control group's 4.07 days. The intervention group also showed an increase in reported physical activity, averaging 5.64 days of at least 30 minutes of activity, compared to the control group's average of 4.87 days. However, there were no significant differences in fruit and vegetable consumption, spacing of carbohydrates, and specific exercise sessions between the two groups. Overall, the intervention has demonstrated a positive impact, as indicated by the self-reported increase in adherence to the eating plan and physical activity levels. It is worth noting that participants themselves reported these improvements in their diet and activity levels. Lastly, the 7-item questionnaire showcased good reliability within our study context, demonstrated by a Cronbach's alpha for internal consistency of 0.83. Tables 5.19 and 5.20 below provide additional information on the differences before and after the intervention.

Table 5-19: Participants' responses average for the diabetes self-care activity questionnaire for both groups at baseline

Statistics

		On average, over the past month, how many days per week have you followed your eating plan? (At the baseline)	On how many of the last seven days did you eat five or more servings of fruits and vegetables? (At the baseline)	On how many of the last seven days did you eat high fat foods such as red meat or full-fat dairy products? (At the baseline)	On how many of the last seven days did you space carbohydrates evenly through the day? (At the baseline)	On how many of the last seven days have you followed a healthful eating plan? (At the baseline)	On how many of the last seven days did you participate in at least 30 minutes of physical activity? (At the baseline)	On how many of the last seven days did you participate in a specific exercise session (such as such swimming, walking, biking) other than what you do around the house or as part of your work? (At the baseline)
N	Valid	29	29	29	29	29	29	29
	Missing	0	0	0	0	0	0	0
Mean		2.62	2.90	3.10	2.07	2.41	3.41	2.38
Std. Deviation		1.821	1.718	1.589	1.534	1.637	1.900	1.656
Minimum		1	1	1	1	1	1	1
Maximum		7	6	7	7	6	7	7

Table 5-20:Participants' responses average for the diabetes self-care activity questionnaire for both groups at the endpoint

Statistics

		On average, over the past month, how many days per week have you followed your eating plan? (At endpoint)	On how many of the last seven days did you eat five or more servings of fruits and vegetables? (At endpoint)	On how many of the last seven days did you eat high fat foods such as red meat or full-fat dairy products? (At endpoint)	On how many of the last seven days did you space carbohydrates evenly through the day? (At endpoint)	On how many of the last seven days have you followed a healthful eating plan? (At endpoint)	On how many of the last seven days did you participate in at least 30 minutes of physical activity? (At endpoint)	On how many of the last seven days did you participate in a specific exercise session (such as such swimming, walking, biking) other than what you do around the house or as part of your work? (At endpoint)
N	Valid	29	29	29	29	29	29	29
	Missing	0	0	0	0	0	0	0
Mean		4.45	4.38	3.83	4.28	4.79	5.24	4.45
Std. Deviation		1.502	1.425	1.692	1.251	1.398	1.480	1.703
Minimum		1	1	1	1	2	1	1
Maximum		7	7	7	7	7	7	7

5.2 Qualitative Results

5.2.1 Introduction

This section reports the results related to the suitability and acceptability of health coaching for patients with T2DM, as well as the perceptions of health coaches and participants based on their views and experiences. A total of 1691 minutes of coaching sessions (84 sessions) were recorded and analysed (see Tables 5.6-5.10). Four hundred and ninety-seven minutes of audio were transcribed for the focus groups and interviews. An Arabic native speaker reviewed the entire transcription for accuracy. To ensure accuracy and validity, a 10% sample of the transcription (approximately 50 minutes) was translated from Arabic to English, back-translated, and then examined by a professional native speaker. All interviews and focus groups were conducted online (video and audio call) due to COVID-19 restrictions.

5.2.2 Results of interviews and focus groups with participants and health coaches

All focus groups and interviews were conducted by the researcher, providing the opportunity to ask questions, interact with participants, and understand their perspectives on the intervention. All data, including coaching sessions, focus groups, and interviews, were audio recorded. A total of 14 semi-structured interviews were conducted between June 15th and September 23rd, 2021. Seven participants from the intervention group were invited to participate in pre-and post-study semi-structured interviews, four of whom were males, and three were females. Most interviewees (n=4) had a high school education or less and chose not to share their monthly income. The participants' median age was 59, ranging from 43 to 62 years. Three of the seven had diabetes for more than ten years, three for less than three years, and one was unsure about the duration of diagnosis. Six of the seven interviewees were using diabetic medication.

Two focus groups were conducted online after the end of the study. The first focus group included six participants from the intervention group, three men and three women, with a median age of 52.5 years (ranging from 34 to 60 years). Three participants preferred not to disclose their monthly income, while the remaining three earned less than 10,000 SR. Most participants (n=5) had a high school education or less, with only one having a bachelor's degree. Most of the focus group participants were on diabetic medication, with four having been diagnosed with diabetes for three years or less. One participant had diabetes for more than ten years, while another was unsure about the duration of their diagnosis. Table 5.21 shows the demographic characteristics of the participants in qualitative interviews (n=7) and focus groups (n=6).

The second focus group was conducted with health coaches to capture their experience in delivering the intervention. All three female health coaches (HC01, HC02, and HC03) were invited to an online focus group which lasted for 265 minutes. All of them had backgrounds in health coaching, and two held a master's degree in health education (HC01, HC02). All of them worked as health educators at KFMC in Riyadh.

Table 5-21: Participants' demographic characteristics

		Qualitative interview participants (n=7)		Focus group participants (n=6)	
Demographic characteristics		Number	%	Number	%
Gender	Male	4	57.1	3	50
	Female	3	42.9	3	50
Age	Years	43 to 62	Median 59	34 to 60	Median 52.5
Marital status	Married	7	100	6	100
Monthly income	less than 5000	1	14.3	2	33.3
	5000-10000	1	14.3	1	16.7
	10000-15000	1	14.3	0	
	Prefer not to declare	4	57.1	3	50
Education level	Primary school	2	28.6	1	16.7
	Secondary school	2	28.6	1	16.7
	High school	2	28.6	3	50
	Bachelor's degree	1	14.3	1	16.7
Since when you were diagnosed with Type 2 diabetes	less than a year	2	28.6	1	16.7
	1-3	1	14.3	3	50
	more than 10 years	3	42.9	1	16.7
	do not know	1	14.3	1	16.7
Do you use diabetes medications?	Yes	6	85.7	5	83.3
	No	1	14.3	1	16.7

5.2.3 Thematic analysis

The thematic analysis process used both inductive and deductive coding approaches. It commenced with bottom-up inductive open coding, where the raw data was examined to

identify potential emerging themes. This initial phase was followed by deductive coding, guided by qualitative research in feasibility studies and the MRC framework [172].

By conducting a thematic analysis of exact quotes from the translated transcripts, various themes and sub-themes were identified. The analysis revealed four key themes, with the first two themes predetermined [172]. The first theme focused on the trial design, conduct, and processes, encompassing four sub-themes that explored various aspects of the intervention's implementation. The second theme discussed the intervention's content and delivery, with four sub-themes addressing intervention components, perceived consequences, feasibility, and acceptability in practice, and reach and dose. The third theme examined the intervention mechanism, incorporating three sub-themes: application of the COM-B model, use of BCTs and the intervention curriculum, and intervention impact. The fourth theme discussed the future RCT and encompassed participants' and coaches' suggestions for further research. Figure 5.7 outlines the thematic map used in the analysis.

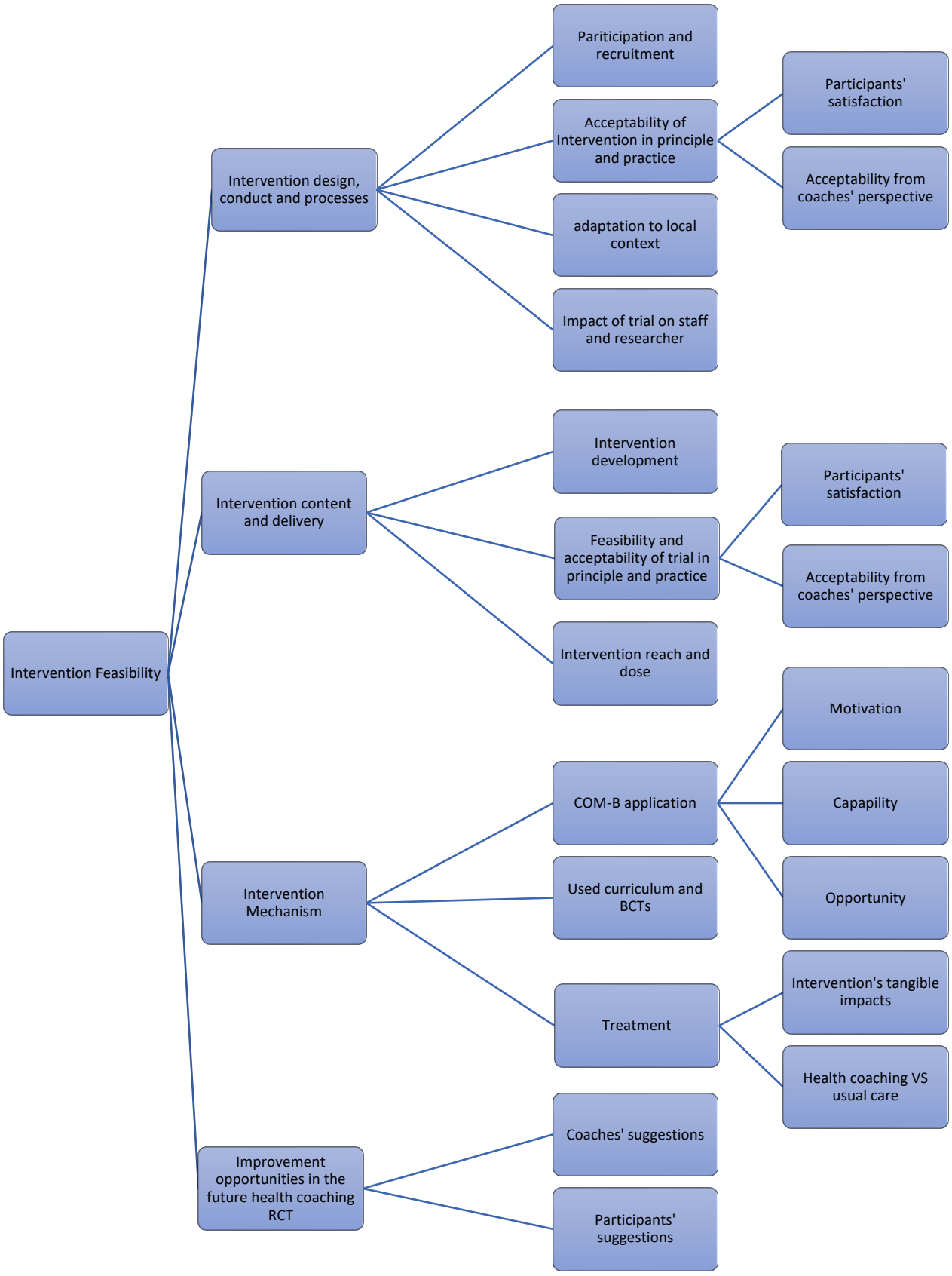

Figure 5-7: Thematic analysis map

5.2.3.1 Theme 1: Intervention design, conduct, and processes

Under this theme, different views were analysed to assess whether the planned recruitment worked in practice, especially during the challenging time with the governmental restrictions because of the COVID-19 pandemic. It is worth mentioning that during the recruitment phase, all the diabetes clinics switched their face-to-face work to remote clinics. As a result, the recruitment was challenging to carry out and took longer than planned time as mentioned earlier in this chapter. Health coaches shared their challenges regarding recruitment at KFMC. We also discussed potential reasons that led participants to drop out during the intervention and examined to what extent the recruitment practices need improvements to recruit a large number of participants.

The concept of health coaching is relatively new in SA, so recruiters' lack of understanding might result in inaccurate information being communicated to patients about the intervention offered. For example, when the researcher first communicated with the intended department's coordinator to explore the possibility of conducting the study at the KFMC, it was apparent that the coordinator had insufficient, ambiguous information on the concept of health coaching. There is a need for recruiters to improve their trial communication, so they can effectively advertise and explain the intervention to potential participants.

"...from my communication with recruiters, some of them did not understand, so participants may get a wrong idea" (FGC, C01, Female)

Due to restrictions imposed by the Saudi public health authority, which severely limited regular access to hospital services for both patients and staff, the recruitment process for the study faced significant challenges. However, following the suggestion from the KFMC

administration to change the intervention site and recruit patients from Al-Zulfi general hospital, which was not yet subjected to the same restrictions, the recruitment process became feasible. Many participants were recruited through physicians and the diabetes clinic. The health coaches noted that the main obstacle was the ability to see and meet patients rather than recruiting them. They believe that recruiting a large number of people for future trials can be achieved, especially when conditions return to normal.

"...I mean the recruitment phase, it was complicated only because all clinics became online and we could not see people with type 2 diabetes come to the hospital as usual, so the chance of meeting those people was very rare." (FGC, C01, Female)

"*…the recruitment should not be difficult in normal conditions…*" (FGC, C01, Female)

There are different ways to recruit patients with T2DM for a trial of a coaching intervention. However, involving physicians in this process as intermediaries is likely to be crucial for a number of reasons. Patients are more likely to follow their physicians' advice due to the trust and credibility they might have in their physicians. In addition, patients tend to have a personal relationship with their physicians, which could lead physicians to recommend an intervention that meets the patient's needs, given that health coaching is a patient-centred approach.

"*…. I think one of the best and most reliable ways to reach and recruit patients is to start from their direct physicians by suggesting the programme for patients and encourage them to join*" (FGC, C02, Female)

Physicians are also able to identify patients with relatively poor glycemic control, who are likely to benefit more from the intervention than patients who already have good control, reflected by having HbA1c measures in (or close to) non-diabetic values.

Participants provided different perspectives on the best ways of advertising for the intervention and recruiting participants, given that the role of social media in SA is vital, where many people communicate through different ways, such as WhatsApp, Snapchat, and Twitter. It was clear the importance of using such methods to access targeted people during the recruitment phase. Due to the significant role of social life in SA, social networks like families and friends were also recommended to use as a method to advertise the intervention.

"*.. advertisement about the program on social media like Snapchat or WhatsApp*" (FG, P05, Female)

" …… *social media is a good way to advertise your program like advertising via Twitter on the city account..... Also, I would recommend recruiting people by their social network like relatives and friends" (*FG, P03, Female)

They also discussed ways of minimising dropouts by screening those who responded or making the commitment involved clearer. Participants emphasised the need to explain the program to future participants at the beginning and to allow them to understand what they will encounter to improve retention and decrease the dropout rates.

"*You should ask them at the beginning if they have any intention to withdraw the program and prevent someone from having this opportunity …"* (FG, P09, Male)

"… some people believe that there is no way to treat diabetes, so they join the program just to see what it looks like and then drop out..." (FG, P11, Male)

"*...ask participants to sign a contract to commit and if you are hesitating or you have the intention to withdraw to tell us [referred to program provider] at the beginning to give the opportunity to someone who needs it"* (FG, P03, Female)

Demographics of the intervention sample were generally regarded as appropriate by health coaches. The sample members were both male and female, and ages ranged from 44 to 59, and a large number of them had limited formal education. Health professionals felt the patients' education level was more significant than their age or gender and affected their experience of the intervention.

Also, I remember facing difficulty explaining some medical terms to some of them who had low education levels..." (FGC, C01, Female)

"...sometimes I used the local language to simplify some information…... the only thing we needed was a long time with them" (FGC, C03, Female)

Health coaches felt comfortable coaching men and women participants; likewise, participant males expressed no preference. On the other hand, female participants preferred to work with female coaches. Due to different reasons, such as cultural norms, females believed that they would be more understood by women and felt more relaxed about sharing their lifestyle and other related concerns.

"... In contrast, I've noticed men were more comfortable and engaged" (FGC, C01, Female)

".. gender matters, I would rather be coached by a female" (FG, P06, Female)

".. I am more concerned about how good the person is at coaching, and also, I feel more comfortable when the coach is female..." (FG, P03, Female)

"I have no problem working with male or female coaches as far as they have quality in coaching" (FG, P09, Male)

During the training phase for health coaches, they had a chance to understand and discuss the intervention design and procedures. Heath coaches felt the intervention design was acceptable in principle and practice.

".. I had a background in health coaching, so I had no problem understanding the intervention design and I think it was acceptable to me and the participants…" (FGC, C02, Female)

"In general, the intervention style was good to me and acceptable..." (FGC, C01, Female)

Because the style of health coaching was a new concept in the Saudi context, where participants needed to talk more, discuss, and set goals for themselves, health coaches felt that some participants unintentionally tried to alter some interventions' procedures in practice. Health coaches believed this resulted from the healthcare delivery style that participants were used to, which primarily focused on education.

"... some of my participants, somehow without attention, used the flexibility to change the planned schedules of some of their sessions. Also, I've noticed that some of them tried to take me to give education instead of coaching; we need to be aware of this" (FGC, C02, Female)

"... some participants asked me to write a plan for them to follow and I felt they wanted me to educate them..." (FGC, C01, Female)

All interviewed participants were happy and satisfied with the intervention characteristics and design. They felt the intervention was easy to follow and effectively addressed their needs. It also enabled them to integrate what they gained skills and learned into their daily lives.

".. many of my surrounding people have known about the program and I highly recommend it to them…. I'm very satisfied..." (P03, Male)

".. I'm very very satisfied and I think the program is easy to follow and very acceptable as it gradually improves different skills which last with a patient after the program…it is completely different from other programmes..." (P13, Male)

The intervention was adapted to fit the local context of Saudi society and culture. Both health coaches and patients generally agreed that the intervention design was effectively adapted to fit the Saudi context. The intervention was, therefore, well-received and appeared to be successful in the Saudi context.

"I never felt the intervention did not fit our society" (FGC, C02, Female)

"It is very appropriate to Saudi society... I have not noticed anything in the program did not suit us..." (P07, Male)

It is worth mentioning the fast and radical changes that the Saudi population has been witnessing since the Saudi Vision 2030 was released. As the vision has emphasised the significance of enhancing the life quality of people, it was observed the wide spreading recreation centres and parks encourage people to be more physically active. Participants praised the current positive changes in the environment and society. Participants believed those changes would easily lead the new generations to adopt healthy lifestyles.

".. there is a close park to my house where I go for walking every day... I see many people walking, especially women and this is good. Society is now changing, and many people have become physically active, which was not the case in the past, as you know..." (P03, Female)

" *.. it is an appropriate program, especially now while our society and new generations are changing..."* (P03, female)

The study had some unanticipated negative impacts on the intervention providers. Due to the lack of funding and absence of allocated time off for health coaches, they had to perform their duties as volunteers, which created difficulties in managing their regular work responsibilities alongside intervention tasks, including conducting coaching sessions, keeping track of their participants' progress, and preparing adequately for each session. The workload was one of the unanticipated impacts highlighted by health coaches during the intervention.

"... because I work as a volunteer health coach in the intervention, I did not get a break from my work, so this adds pressure on me to manage my routine duty... also as you know when we started the program, my work gave me additional tasks, and I could not reject it because the intervention was a voluntary task... it was a really tough situation to handle" (FGC, C01, Female)

"For me, the main harm was conducting sessions on weekends or after my daily work when a participant asks to reschedule any session, it was a bit annoying" (FGC, C01, Female)

The health coaches advised seeking permission and support from their workplace so they could fully commit to implementing the intervention's many activities and have enough time to work full-time until the intervention is completed.

"Coach should get approval from their work to have a break from work and then work full time in the intervention to ensure that the coach gives the intervention enough effort" (FGC, C02, Female)

".. As you know and because of the workload, I was thinking of withdrawing from the intervention..... I think it is imperative to work a full-time job as a health coach in the intervention, not as a volunteer, and get formal permission from my work on this..." (FGC, C01, Female)

The COVID-19 epidemic made it more difficult since some participants, particularly women with children, needed more flexibility in their scheduled coaching sessions as all schools went online. They needed to be with their children while studying. As a result of the workload and flexibility, several coaches worked harder to find time; some delivered coaching sessions from home after leaving the workplace (KFMC).

" *.. because of the pandemic, some participant and especially women were busy throughout the day with their children [All schools switched to online class], so scheduling their sessions were challenging because they mostly could not take session in the morning as I preferred, so I had to reschedule their sessions after finishing my work at home, which I was supposed to spend with my family*" (FGC, C02, Female)

"The *most challenging thing was the conflict between my routine duty at work and the intervention, especially when participants asked me to reschedule a session. Participants should commit to their scheduled sessions as they can*" (FGC, C01, Female)

5.2.3.2 Theme 2: Intervention content and delivery

This theme has different sub-themes, which all relate to the implementation of the intervention. The first sub-theme highlighted the extent to which the intervention has to be adjusted and adapted in order to be more acceptable in the Saudi context. The second sub-theme was focused on the perceived harms or unintended consequences resulting from the intervention. The third sub-theme highlighted the feasibility and acceptability of the intervention implementation in practice. Finally, the intervention reach and dose were the fourth sub-theme.

Health coaches shared their views on how to improve specific components of the intervention to make its content more acceptable and appropriate for the Saudi context. All coaches agreed that making slight amendments to the intervention would significantly impact its implementation in practice. The key objective they mentioned was to make the intervention delivery style appear more professional.

".. the communication with the participant through a formal platform or application, you know, like how the clinics communicate with patients here in this hospital [KFMC]to make the program more formal and organized for both patients and the coach, so everyone knows their schedule, plans, and goals to be more professional than phone calls..." (FGC, C02, Female)

"The sample I dealt with was older people, so I think they would not take voice calls as seriously as actual visits to a clinic… Personally, I prefer to have a physical meeting where I can sit with the patient face-to-face, which would give the program more formality and professionality image and give the participants a sense of how the program is serious." (FGC, C01, Female)

As unfunded research, there was no reserved place at the hospital for health coaches to deliver coaching sessions. All coaches emphasised the administrative side of the program, which involves having a dedicated room prepared for coaching sessions and giving a sense of professionalism for the intervention.

".. As a coach, there should be a certain prepared privet place at work to conduct all of my coaching sessions..." (FGC, C02, Female)

"One of the biggest challenges I faced was having a private place to conduct coaching sessions with participants..." (FGC, C03, Female)

".. we only have one room in our department which is the shared room for all of my colleagues at work, so sometimes this room was unavailable, and it was difficult to find and book a quiet private room in the hospital..." (FGC, C01, Female)

According to all health coaches, visual coaching sessions are preferable over phone coaching. This implies that the coaches feel that having visual contact with the client during sessions is critical for good communication and coaching. Two coaches believed that video calls were

adequate and in-person meetings were unnecessary. Consequently, coaches appear to prefer the visual part of coaching sessions and the opportunity to see their participants throughout sessions to achieve the best coaching results.

"...the majority of the sessions were phone calls. We want to make it more formal through face-to-face, video sessions and this was what I grasped from the participants; they prefer video calls" (FGC, C02, Female)

".. one of this program's features was the flexibility, so I think if we asked participants to attend the hospital, it would be hard for some of them to complete the intervention… visual interaction with participants is very important, you know the importance of reading and understanding the body language for me as a coach..." (FGC, C03, Female)

"Without a doubt sitting with participants face-to-face is the best way to carry out the health coaching program but to combine our perspective with participants' perspectives, a visual online meeting is the best option..." (FGC, C02, Female)

Participants described the intervention's implementation procedures as simple to follow. They believed that the way the intervention was implemented helped them make progress and achieve desirable outcomes. Although most of them thought that the intervention duration was acceptable, some stated their desire for additional sessions to help them sustain and adapt to the new habits and skills they gained.

"I have not noticed that the program was complicated or difficult and mostly after the first or second session, the program becomes clearer... for me, I think 3 months was enough" (P03, Female)

".. it was a very easy program, I have no problem with it…it enabled me to stay committed continue and achieve my goals" (P09, Male)

Using health coaching techniques such as an action plan and SMART goals to set realistic, achievable goals helped participants gradually make meaningful progress. They felt this was a key factor in staying motivated and made the intervention more accepted and easier to follow. They appreciated the intervention level of flexibility used in its structure.

"To be realistic, the program is easy to follow, and the thing that helped me a lot was the flexibility and easy communication, not to mention the realism of the program from the perspective of goals and action plans to overcome barriers and the most thing I liked about the program was the graduality to achieve goals ..." (P13, Male)

All health coaches felt the intervention content was acceptable in principle and practice.

" .. I think the intervention design is appropriate and the positive impacts were observable and were the best indicator and evidence..." (FGC, C02, Female)

"*...the content worked well with me in practice... and I could see how my patients accepted it"* (FGC, C01, Female)

" .. my experience was good, and I would join again if I had the opportunity..." (FGC, C03, Female)

Two health coaches thought that the number of coaching sessions was acceptable. They did, however, advise that three monthly sessions be added to help patients who need more time to maintain or make further progress. At the same time, one health coach recommended a six-month intervention with monthly sessions.

"... I think the number of sessions was adequate, but it would be better if we had more sessions... I would suggest a minimum of six sessions within three to five months and maybe a monthly session in the last three months of the intervention....." (FGC, C02, Female)

".. as for my participants, the number of sessions was appropriate, but I suggested more sessions, a maximum of six months, to be able to monitor the impacts and progress that a participant achieves... as I told you before, some of the participants asked me to continue with them to help them maintain progress..." (FGC, C03, Female)

".. In regard to the intervention and number of sessions, it was enough but, in the future, I suggest the intervention last longer… I think it would be good if the intervention lasts six months with a session each month …" (FGC, C01, Female)

5.2.3.3 Theme 3: Intervention Mechanism

This theme explores how COM-B was used in practice to deliver health coaching activities. It also explores how the intervention's curriculum was implemented and whether it helped

coaches deliver the intervention as planned. The treatment subtheme examines and reports the preliminary effects of the intervention and the difference between usual care and health coaching.

Health coaches received training on the intervention curriculum and how to use BCTs in practice. They also used different tools, like a guidance form that provided more details to help coaches carry out sessions as planned (see Appendix 10). Each coach was asked to document the BCTs they use in each session. Different BCTs were reported in each session. Coaches believed that the curriculum helped them facilitate each session. In addition, using BCTs enabled them to effectively select specific techniques to target any behaviour that needs to be addressed.

"As a health coach, it is the first time I come across a health coaching program built in this way; I mean I liked how the BCTs were framed... it helped me during each session to address some behaviours…" (FGC, C01, Female)

".. it was very helpful using the curriculum and the main detailed operational schedule..." (FGC, C01, Female)

".. I followed exactly the intervention guidance… you know ... I used the schedule in each session, so it helped me to remember the content of each session and the goals, and skills that need to be discussed with a participant... it helped a lot to prepare myself before each session…" (FGC, C03, Female)

"...it was useful [the curriculum] … you know to have proposed techniques targeting different behaviours, so as a coach, you know you do not need to waste time on this… I just needed to select appropriate techniques to build new behaviours or change others..." (FGC, C01, Female)

The COM-B model was used to operationalize the mechanism of the intervention targeting the four behaviours. Under each model category, Capability, Opportunity, and Motivation, participants' experiences and views were captured to understand how they perceived it in practice. Generally, participants expressed satisfaction with the changes and progress related to their knowledge and motivation before and after the intervention.

Following the intervention, participants reported an improved general awareness and understanding of diabetes and the importance of modifying their lifestyle. They felt more knowledgeable about diets, nutrition, and physical activity. Some participants regarded the increase in their knowledge as the most significant outcome of the intervention.

" .. Thanks God... I feel that I became more knowledgeable and educated about my condition... and I can see myself now much better… now I know diet types and what carbohydrates mean..." (FG, P05, Female)

".. Big difference! I'm not exaggerating... before the intervention, my knowledge was below zero regarding a healthy diet and the importance of being physically active. I did not know the relationship between diseases, especially diabetes and blood pressure, and my behaviours and lifestyle [laughs]." (FG, P09, Male)

".... Oh God, I'd say I'm 100% changed... It is really a big change, the difference in my knowledge now like the difference between the earth and the sky [referring to the distance] I wish I had the awareness just 3 years ago... the program reshaped my thinking about diabetes and the way of choosing what I eat, food types, and what good and bad behaviours directly impact my blood sugar, now I'm more active and walk daily and I can see the difference.." (P013, Male)

*".. thanks God, thanks God… it's a big jump and changes in my knowledge; I started to use healthy diet alternatives. For example, Stevia, instead of regular sugar, reduced the daily carbs, and I could notice the positive impacts... now I know how to find reliable information about diabetes; I became more interested in reading about calories and nutrition in general and transferring what I read and learn to other people with diabetes" (*P03, Female)

".. frankly, my knowledge improved regarding a healthy diet and the importance of physical activity; I could reduce the quantity of rice, pasta, and dates and have more vegetables. I eat food containing more fibre, I become more physically active than before... I do not know, but I feel my fitness has improved…" (P06, Female)

Participants described how the social and physical environment influenced their condition and provided opportunities to engage in the intervention activities. They acknowledged that the general environment in SA was not encouraging in the past, but they highlighted positive changes in recent years that have enabled them to adopt a healthier lifestyle. Participants also believed that the intervention had an impact on their social network, suggesting that it influenced the attitudes and behaviours of those around them.

"... while I was changing some of my old habits, my social network has adapted to the new situation... they were really supportive..." (P03, Female)

".. not only me who benefited from the program but also my family has become more educated now regarding a healthy diet [laughs]... people now changed, in the past it was not easy for me to wear sports clothes and run or walk outside, but now this has become normal... you know what, I'm just waiting for the weather to get colder and will take my wife to walk with me [laughs]..." (P09, Male)

".. I think the environment is now encouraging to be active; you can see how many people out there walking..." (P10, Male)

Given the tailored nature of the health coaching intervention, participants felt that it empowered them individually to become and stay motivated in taking charge of improving their condition. They believed that the intervention supported them in changing their perspective on diabetes and enabled them to enhance their self-learning about the condition. As a result, many of their old beliefs and convictions about diabetes changed, and they found it easier to adopt new healthy behaviours.

".. the awareness about diabetes consequences on my health motivated me to change my mentality and to accept new positive changes in my life... you know what the funny thing? I thought it was impossible to control diabetes without medications, but after the intervention, I

realised modifying the lifestyle is the actual treatment and at the same time it is not a difficult thing to do as I was thinking" (P13, Male)

The most significant factor that enhanced their motivation was the noticeable differences in certain outcomes, such as their HbA1c levels before and after the intervention.

"After the program, I can see my A1c has declined and my blood sugar is stable, which encouraged me to continue controlling my blood sugar... my fear of diabetes complications motivated me to take care of myself..." (P09, Male)

".. the last blood test reflects my good diabetes self-management and my willpower to maintain the progress" (P03, Female)

Participants appreciated the intervention for allowing them to explore their motivation and capabilities. One of the main objectives of the health coaching program was to encourage participants to identify and prioritise their health goals through a realistic and achievable action plan. Participants were able to reassess their health priorities and develop a better understanding of their strengths and weaknesses through the coaching sessions.

".. to know that this disease is directly related and influenced by my lifestyle. I mean changing some habits would lead to a big positive difference in my health, ... this was the biggest lesson I learned from the program, and if this would be the only benefit, I got from the program it would be enough to motivate me to maintain the healthy lifestyle..." (P013, Male)

*".. now I reorganized my priorities, so controlling my condition is now my priority... it was not before the intervention" (*P06, Female)

The observable impacts of the intervention played a significant role in motivating participants to continue their progress and subsequently increased their satisfaction with the intervention. As a result of the tangible outcomes, such as reductions in A1c levels and body weight, some participants expressed a desire to extend the intervention duration. Participants were pleased with the measurable improvements they achieved through the intervention.

".. I' 'm happy because my weight decreased by 3 kg, and this was my main goal when I started. Also, my blood sugar improved. Before the intervention, the fasting blood sugar was 147 but now 107; this is because of you, I do not know how to thank you..." (P03, Female)

".. number talks, when I started the program, the A1c was 11.5% and now is 5.8%..." (P13, Male)

".. I changed many behaviours like using a spoon in eating and avoiding food enriched with carbohydrates, such as white bread and dates…I'm very happy about the achievement, at the beginning, the A1c was high, I do not remember exactly, but now it is about 7.2%..." (P08, Male)

Because health coaching is a new concept in SA and differs from traditional care, participants described the main differences they have noticed. They believed that health coaching provided a more personalised approach compared to usual care, allowing them to openly discuss and

address their concerns. Participants expressed frustration with the current care they receive and expressed gratitude towards health coaches for their acceptance, flexibility, and attentive listening to their concerns. They felt that health coaching offered a higher level of support and attention to their individual needs.

"If I were asked to choose one [usual care vs health coaching], I would choose this program without hesitation; at least I finish each session while I'm comfortable... I just need someone to sit with me, listen to me, and discuss what concerns me, like the coach who worked with me" (P03, Female)

".. no comparison, those programmes [referring to usual care]do not speak with our society, and its impact is suboptimal, not to mention that your program works on individual levels whereas the others are too general..." (P13, Male)

The usual care style was perceived as different from health coaching by the participants. In usual care, participants felt they were passive recipients of information or pre-prepared plans without much engagement or involvement in the process. However, in health coaching, they viewed themselves as active participants and felt empowered to take ownership of their health by actively planning and setting goals for themselves. They appreciated the collaborative and empowering nature of health coaching, where they played a central role in their own health journey.

".. in the beginning, I thought your program would be providing information as I used to... your program helped me use some new skills such as setting plans and having short-term and long-term goals… it is good to have someone listen to you as the coach once said (I will work with you as a friend)... she accepted my complicated condition and was flexible and following up with me..." (P08, Male)

"... I used to follow what I was told to do from my physician and was not really aware of my condition like now..." (P09, Male)

"... the difference is very big; some people I know who follow the usual care and did not have information and did not change their lifestyle have died, may Allah give them a mercy, they died because of diabetes and its complications..." (P07, Male)

Most participants shared similar feelings about the usual care they receive, expressing frustration and, in some cases, anger. They expressed dissatisfaction with their routine doctor visits for various reasons. The limited time allocated for each visit placed them under pressure to discuss their concerns within a few minutes. Participants felt that their doctors showed little interest in providing comprehensive care or offering empathy to help them manage their disease, with the focus being primarily on prescribing medications. As a result, some participants felt compelled to seek care at private hospitals where they could spend more time engaging in meaningful conversations and discussing their concerns.

".. the routine visits to my doctor at the hospital were really frustrating for so many reasons... I think the common thought among doctor*s is that people over 40 years old must start taking medications; they literally get me into a frustration cycle..."* (P03, Female)

".. I was badly waiting for my appointment with my doctor [Ah]. Do you know how long the appointment was? It was one and a quarter minute!! Even though I was standing, all what he said, "your A1c is BLA BLA…… and then asked me to go to the hospital pharmacy to get the prescription!! No way!! Where are we living? At least he did not take my blood pressure and weight, my weight decreased, and he did not ask about reasons, and he did not discuss anything with me... (P03, Female)

"I honestly have my routine visits with a private hospital just to find time to discuss with a doctor and listen to me and I think many patients like me have the same problem..." (P06, Female)

Participants recognised the value and significance of health coaching and suggested that hospitals should establish health coaching clinics. They believed that having health coaches available in hospitals would benefit patients and relieve the burden on medical care. Participants expressed the view that health coaches could engage in meaningful discussions with patients, helping them understand their health problems and empowering them to take control of their diseases. They believed that many patients with chronic diseases would greatly benefit from the support of a health coach, enabling them to develop various skills for better self-management and engaging in meaningful conversations about their health.

"I suggest that, and you must have a role in the hospital; why do not you have a clinic in the hospital so other patients can have an opportunity to sit with a coach. I'm willing if you want me to make a communication with the health authority and request this…" (P13, Male)

".. I think it is important to recruit a coach in the hospital... there is a gap between patients and doctors; the program will effectively bridge the gap. I think 90% of patients with chronic diseases need to sit with someone to have meaningful discussions to understand the real problems..." (P08, Male)

5.2.3.4 Theme 4: Improvement opportunities in the future health coaching RCT

While an observational study has recently introduced health coaching in primary care settings in SA for weight loss[22], its application for T2DM remains unexplored in a randomised controlled trial setting. Therefore, we aimed to gather participants' feedback and suggestions in our feasibility RCT to refine and inform the future large-scale intervention. Participants provided different feedback to enhance the efficacy of future interventions. They expressed that increasing the intervention dosage by having more frequent coaching sessions would lead to better outcomes. Additionally, participants preferred the inclusion of more face-to-face sessions. Furthermore, they recommended offering the intervention to patients with a high level of commitment and uncontrolled diabetes, as they believed these individuals are more likely to benefit from the program and less likely to discontinue their participation.

".. I would rather have a longer time with you and more face-to-face sessions" (P01, Female)

".. I would suggest that you choose patients who do not have the background about diabetes because they will benefit more..." (P7, Male)

".. I prefer face-to-face sessions and more than 3 months in order to maintain the progress we make" (P9, Male)

".. I suggest you include requirements at the beginning for people who want to join the program like no withdrawal during the program..." (P03, Female)

Health coaches provided valuable suggestions to consider when conducting a future RCT of health coaching. Recognising that diet and medication are directly linked to diabetes management, the coaches recommended the inclusion of a dietitian and physicians for easy referral, as it would enhance the overall outcomes of the intervention. This would allow coaches to seek quick consultations or make referrals when participants have specific questions or needs. Furthermore, the coaches suggested having regular meetings to facilitate discussion of their experiences and learn from one another, promoting continuous improvement and sharing of best practices.

".. one of the modifications I suggest is having a nutritionist and a physician in the program so we can refer some participants to them for specific consultations or if they have questions..." (FGC. C03, Female)

"... I'd suggest including frequent meetings for health coaches to discuss anything related to the program so we can benefit from each other..." (FGC. C01, Female)

For the future implementation of the intervention, health coaches recommended the provision of incentives to encourage participation. They suggested that incentives could take the form of financial rewards or increased access to hospital facilities and services. By offering incentives, such as a direct and quick connection with their physicians, participants may feel motivated and engaged in the intervention, leading to better outcomes.

"...participation in the intervention may require providing incentives like money" (FGC, C01, Female)

"*…since the intervention was not funded, we may provide other alternatives, such as providing additional care access to the health services, making them special…. We can provide them easy and direct contact with their physicians or if there any other services we can provide…."* (FGC, C03, Female)

Health coaches provided suggestions to consider for the future large-scale RCT. One suggestion was to create a short video that explains the concept of the health coaching program to participants. The video would include a real-life example of a health coaching session, allowing participants to have a clear understanding of what to expect from the program. By providing this video, the health coaches believe they can save time that would otherwise be spent clarifying the concept of health coaching and focus more on delivering the intervention effectively.

"...the idea of patient-centred style was not clear enough at the beginning for some participants and I remember one of my patients said "why you skimp with your knowledge" [laughs]…. I would suggest creating and sharing a small video explaining the idea of health coaching" (FGC, C02, Female)

"...it is good to create and share two to three minutes example video of health coaching example during the recruitment phase to introduce the intervention very well" (FGC, C01, Female)

" I think the main issue was the confusion participants had about the idea of health coaching; some of them thought the essential idea of the program was to follow a specific plan prepared by us and seemed like they were waiting for something from us [laughs], which is normal for someone used to have usual care by following doctors guidance., so it is important to keep this in mind from the begging and avoid wasting time clarifying the idea of health coaching" (FGC, C01, Female)

5.2.4 Integration of qualitative and quantitative results

The term "integration" is used to describe the way qualitative and quantitative data components interact in research [176]. To compare these two types of data, a joint display table is a useful tool that clearly shows how the data were combined. Different signs are used to indicate the outcome of combining the two sets of data. The "=" sign indicates convergence, the "+" sign indicates that the data complement each other, and the "≠" sign indicates inconsistencies between the two approaches (see Table 5.24)[178].

Key findings from quantitative and qualitative data and the research objectives were tabulated side by side in a joint display table [140] (see Table 5.22). The first column reflects the study's key concepts, and the second column includes the study progression criteria, providing further explanation of the findings from the mixed methods. The third and fourth columns represent quantitative and qualitative results related to the key concept. The last column reflects the generated meta-inferences resulting from the integration of data.

Table 5-22: Joint display table

Key concepts	**Predetermined progression criteria**	**Predetermined Cut-off criteria results**	**Quantitative results**	**Qualitative results**	**Integration result (Morgan, 2013).**	**Integration (meta-inference results: converge, diverge, or extend)**
Screening prospective participants	If 60–80% or more of those eligible to participate in the study consented, this supports conducting a large RCT scale trial, but if the percentage is less than 50%, there is no significance moving forward.	> 80% screening rate (this suggests proceeding to the future definitive RCT)	38 out of 42 participants were eligible to participate in the study (screening rate: 90%)	No data	=	The screening rate was high and exceeded the study progression criteria. The study's inclusion criteria were appropriate to target the potential population.
Recruitment rate	If the recruitment rate of people who were eligible and consented was ≥80%, this would support conducting a large RCT trial. If the rate was between 70–65%, this needs further discussion to explore the reasons and whether, if they	> 70% recruitment rate (this suggests reconsidering before proceeding to the future definitive RCT)	30 out of 38 participants consented and enrolled in the study (recruitment rate: 79%)	*Theme 1: subtheme 1: participation and recruitment:* "*…the recruitment should not be difficult in normal conditions…*" (FGC, C01, Female) *".. recruiting more people will be achievable based*	=	Converge Justification: The recruitment rate was high and nearly met the study progression criteria. Qualitative data confirmed that participants were

Key concepts	Predetermined progression criteria	Predetermined Cut-off criteria results	Quantitative results	Qualitative results	Integration result (Morgan, 2013).	Integration (meta-inference results: converge, diverge, or extend)
	can be modified, then the trial may progress with caution. If the rate was ≤65%, there is no significance to moving forward.			*on what I've seen from participants' reactions..."* (FGC, C02, Female) *".. some participants asked if it is possible to enrol some of their relatives or friends in the program..."* (FGC, C03, Female)		happy to join the intervention and they would encourage other relatives and friends to join. From the researcher's observations, there were a number of calls from other people requesting to join in the future
Retention rate at 3-months	If the rate was ≥83%, this supports conducting a large RCT scale trial. If the rate was less than 83%, there is no significance to moving forward.	> 83 % retention rate at 3-months (this suggests proceeding to the future definitive RCT)	29 out of 30 participants completed the study (97%). Only one participant has withdrawn before the first session	Only one person withdrew before the first session. The participants reached out to explore the possible reasons, which involved a family concern. Participants emphasised the importance of commitment as they valued participation in the intervention and believed the opportunity should only be given to a committed person. "*You should ask them at the beginning if they have any intention to withdraw the*	=	Converge Justification: Given the circumstances and restrictions imposed such as multiple lockdowns due to COVID-19, the retention rate was high. This fact was emphasised by the participants' experience (QUAL) during the intervention.

Key concepts	Predetermined progression criteria	Predetermined Cut-off criteria results	Quantitative results	Qualitative results	Integration result (Morgan, 2013).	Integration (meta-inference results: converge, diverge, or extend)
				program and prevent someone from having this opportunity …" (FG, P09, Male)		
Intervention adherence	If the adherence rate was ≥84% of the intervention (≥5 out of the 6 coaching sessions). If the rate was between 84–67% (≥5.4 out of the 6 coaching sessions), this needs further discussion to explore the reasons and whether, if they can be modified, then the trial may progress with caution. If the adherence rate was less than 67%, there is no significance in moving forward.	>84% of the intervention (≥ 5 out of the 6 coaching sessions) (this suggests proceeding to the future definitive RCT)	All participant in the intervention group completed all their coaching sessions (adherence rate 100%)	*Theme 2: subtheme 4: reach and dose of the intervention:* All participants completed their sessions despites the 11 rescheduled sessions. In general, they were happy and requested to have more sessions *"…I suggested more sessions, a maximum of six months, to be able to monitor the impacts and progress that a participant achieves... as I told you before, some of the participants asked me to continue with them to help them maintain progress..."* (FGC, C03, Female) *".. I prefer face-to-face sessions and more than 3 months in order to maintain the*	=	Converge Justification: The adherence rate exceeded the progression criteria Qualitative data emphasised and explained the high adherence rate Many participants expressed their desires by suggesting increasing the number of coaching sessions The way health coaches delivered the sessions contributed to improving participant adherence and commitment.

Key concepts	Predetermined progression criteria	Predetermined Cut-off criteria results	Quantitative results	Qualitative results	Integration result (Morgan, 2013).	Integration (meta-inference results: converge, diverge, or extend)
				progress I make" (P9, Male)		
Secondary measurements acceptability	No data	No data	All participants completed the measurements' assessments at the study baseline and endpoint: At the baseline: 30 out of 30 (100%) At the endpoint: 29 out of 30 (96.6%) Only one participant has withdrawn before the first session	HbA1C, blood pressure, BMI, weight and waist circumference. Coaches believed the selected outcomes to measure were appropriate *"… measurements served well the main purpose of the program (diabetes)... no need to add new measurements."* (FGC, C01, Female) We asked participants about their experience with baseline and endpoint measurements assessments. *".. I think the same way you did the assessments; it was easy and straightforward..."* (FGP, P03, Female)	=	Converge Justification: Despite the restrictions imposed due to COVID-19, the adherence to data collection was high as all participants in both groups completed their assessments in the planned time Coaches agreed that the secondary outcome assessments were adequate as it covered the intervention purpose Qualitative data confirmed this, as participants felt the data collection process was acceptable
Intervention preliminary efficacy and	No data	No data	Observed improvements were seen across different	Participants were happy about the		Converge Justification:

Key concepts	Predetermined progression criteria	Predetermined Cut-off criteria results	Quantitative results	Qualitative results	Integration result (Morgan, 2013).	Integration (meta-inference results: converge, diverge, or extend)
tangible effects			secondary outcomes: 1- Significant reduction in HbA1c favouring health coaching group: -1.86 (95% CI: -2.71 to -1.01, P<0.001) 2- Weight improvement was seen more in the intervention group: -2.58 (95% CI: -5.25 to .082, P= 0.057) 3- BMI improvement was seen more in the intervention group: -1.02 (95% CI: -2.01 to -.041, P=0.042) 4- larger reduction was seen in the intervention group: -6.89 (95% CI: -10.17 to -3.61, P<0.001) 5- The patients' self-efficacy questionnaire revealed that self-efficacy improved in both groups but was much greater in the	intervention's tangible effects. *".. I' 'm happy because my weight decreased by 3 kg ... Also, my blood sugar improved. Before the intervention, the fasting blood sugar was 147 but now 107..."* (P03, Female) *".. number talks, when I started the program, the A1c was 11.5% and now is 5.8%..."* (P13, Male)	=	Qualitative data confirmed the improvements in the quantitative results

Key concepts	Predetermined progression criteria	Predetermined Cut-off criteria results	Quantitative results	Qualitative results	Integration result (Morgan, 2013).	Integration (meta-inference results: converge, diverge, or extend)
			intervention group.			
Intervention experience	No data	No data	The overall session length per patient ranged from 106 to 153 minutes, with an average of 120.8 (SD= 13.7) Among 36 BCTs, the most used BCTs: *1.3 Goal setting (outcome),* which has been used 43 times with three behaviours targets; decrease carbohydrate intake for each meal, exercise for 30 min five days weekly, and monitor waist circumference *1.7 Review outcome goal (s)* was the second most frequent technique (reported 39 times)	Participants felt the intervention was easy to follow and fits the Saudi Context " *.. it is an appropriate program, especially now while our society and new generations are changing..."* (P03, female) Coaches believed that the curriculum including the COM-B model and BCTs helped them deliver each session as planned *".. I followed exactly the intervention guidance… you know ... I used the schedule in each session, so it helped me to remember the content of each session and the goals, and skills that need to be discussed with a participant... it helped a lot to*	=	Converge Justification: Qualitative data confirmed and explained quantitative results about participants' and health coaches' experience. Participants found the intervention easy to follow and fits the local context Health coaches felt the curriculum was doable and helpful

Key concepts	Predetermined progression criteria	Predetermined Cut-off criteria results	Quantitative results	Qualitative results	Integration result (Morgan, 2013).	Integration (meta-inference results: converge, diverge, or extend)
			Participants responded to one of the related questions (To what extent did participation in health coaching: 1- Increase your use of goal setting skill? 12 participants responded with "Very Much" and 2 responded with "Quite a bit" 2-Increase your use of problem-solving skills? 8 participants responded with "Very Much" and 5 responded with "Quite a bit" and only one participant responded with "Somewhat"	*prepare myself before each session…"* (FGC, C03, Female) *"...it was useful [the curriculum] … you know to have proposed techniques targeting different behaviours, so as a coach, you know you do not need to waste time on this… I just needed to select appropriate techniques to build new behaviours or change others..."* (FGC, C01, Female) *"...your program helped me use some new skills such as setting plans and having short-term and long-term goals..."* (P08, Male)		
Satisfaction with the intervention	No data	No data	Likert-scale Satisfaction Questionnaire revealed that the participants were highly satisfied with the intervention (Likert scale	Overall, participants were satisfied. *".. I'm very very satisfied and I*		Converge Justification : Qualitative data confirmed quantitative results

Key concepts	Predetermined progression criteria	Predetermined Cut-off criteria results	Quantitative results	Qualitative results	Integration result (Morgan, 2013).	Integration (meta-inference results: converge, diverge, or extend)
			questions: 0 (not at all) to 10. (Very much)). Participant satisfaction average rates ranged from 8.14 to 9.21 out of 10. The majority (n=13, 92.9%) responded with "Yes" the intervention met their expectations When asked if they would recommend the intervention to others, all participants (n=14, 100%) responded with "yes"	*think the program is easy to follow and very acceptable..."* (P13, Male) *".. many of my surrounding people have known about the program and I highly recommend it to them…. I'm very satisfied..."* (P03, Female) *"If I were asked to choose one [usual care vs health coaching], I would choose this program without hesitation..."* P03, Female) *"I suggest that, and you must have a role in the hospital; why do not you have a clinic in the hospital so other patients can have an opportunity to sit with a coach... I'm willing if you want me to make a communication with the health authority and request this…"* (P13, Male)	=	about participants' satisfaction
Flexibility in scheduling	No data	No data	Out of 84 sessions, only	The intervention flexibility helped		Converge and qualitative data

Key concepts	Predetermined progression criteria	Predetermined Cut-off criteria results	Quantitative results	Qualitative results	Integration result (Morgan, 2013).	Integration (meta-inference results: converge, diverge, or extend)
coaching sessions			eleven sessions have been rescheduled (13%)	participants adhere to and complete their sessions. *"...the thing that helped me a lot was the flexibility and easy communication…"* "The *most challenging thing was the conflict between my routine duty at work and the intervention, especially when participants ask me to reschedule a session. Participants should commit to their scheduled sessions as they can*" (FGC, C01, Female)	=	further expands justifications for rescheduling sessions for participants. The flexibility helped participants but on the other hand, added to the workload for coaches

5.2.5 Conclusion

Integrating quantitative and qualitative findings has provided further insight into the data collected by both methods and analysed separately. It helped to enhance the credibility and transparency of the overall findings through data triangulation by comparing one to another to confirm or disconfirm the results, which would not be achievable using one method alone. The

results of this integration have supported and demonstrated the relevance of adopting mixed approaches. Given the study's nature as a feasibility study conducted for the first time, it was critical to thoroughly investigate the feasibility and acceptability from various perspectives in order to provide a comprehensive understanding of the potential of implementing a larger-scale intervention with T2DM patients in the Saudi context.

With a screening rate of 90% and a recruitment rate of 79%, the study's rates for screening and recruitment were strong but fell just short of meeting the progression criteria for recruitment The retention rate, however, was 97%. These findings were supported by the integration results of both quantitative and qualitative data. This suggests that the study's potential in the Saudi context is promising, especially in light of the participants' expressed willingness to participate in the intervention, their invitation to family members, and their adherence to and commitment to complete the intervention. Despite some rescheduled sessions, the integration of quantitative and qualitative data on intervention adherence demonstrated the participants' high level of commitment. This was reinforced by the participants' expressed desire for additional sessions in order to maintain the progress made. Despite COVID-19 restrictions, all participants attended assessments before and after the intervention. In addition, improvements were observed in five out of seven preliminary outcomes, which were also supported by the qualitative data. Participants and coaches reported positive experiences with the usability of the intervention, its design, and its content. The qualitative research supported participants' high levels of satisfaction with the intervention, as indicated by the quantitative data, particularly the Likert-scale Satisfaction Questionnaire. Although the flexibility to reschedule planned coaching sessions posed a challenge for coaches, it facilitated participants' adherence to and completion of all their sessions. This fact was confirmed by the quantitative data, which showed that all participants completed all their sessions, while only eleven sessions needed rescheduling.

CHAPTER 6: Discussion

6.1 Introduction

This chapter aims to discuss the quantitative and qualitative findings of the trial of health coaching for T2DM in a Saudi population in more detail, considering both the research objectives and how the findings relate to the existing literature. This chapter: (i) discusses to what extent the intervention was found to be feasible, (ii) highlights participants' experiences and provides a discussion of the intervention mechanism, (iii) discusses to what extent the intervention was acceptable to the participants and intervention providers, (iv) discuss to what extent participants were satisfied, (v) summarises the implications for the future definitive RCT.

6.2 Feasibility of proceeding to a larger-scale study

The main goal of the feasibility study was to lay the groundwork for a larger-scale trial, and the results both demonstrate its feasibility and identify some ways in which both recruitment to the trial and delivery of the intervention could be improved. In our study, the term 'screening rate' represents the proportion of participants deemed eligible from those we initially identified, with 38 out of 42 individuals meeting our eligibility criteria, resulting in a screening rate of about 90%. When compared to the screening rates of 56.4% [185], 55.9% [186], and 88.6% [187] reported in similar health coaching interventions in the existing literature (see Chapter 3), our screening rate of approximately 90% is notably higher. Considering the varying inclusion criteria across these studies and in existing health coaching intervention literature, our specific inclusion and exclusion criteria demonstrated their appropriateness for our targeted group, suggesting their suitability for larger-scale RCTs in the future. However, it's worth mentioning

that our 'screening rate' does not represent all individuals in SA with T2DM but specifically those who met our study's criteria.

Even though the study was conducted during the initial wave of the COVID-19 pandemic, a period marked by significant governmental restrictions and disruptions (as detailed in Chapter 5), and despite the absence of incentives for participants, the recruitment rate came close to meeting the predefined progression criteria at 79%. This percentage signifies that the majority of eligible individuals chose to participate in the study. As health coaches believed recruiting a large number of participants was feasible, qualitative findings validated the high recruitment rate. Furthermore, the recruitment procedure in normal conditions where patients had access to the hospital (Al-Zulfi general hospital) took five weeks, shorter than expected. The recruitment rates presented in the existing literature show diverse outcomes related to the recruitment of their respective samples. According to Basak C & Schou (2013), 90.3% of their sample was recruited[185], while Kim et al. (2015) reported recruitment rates of 90.7%[186], and Cho et al. (2011) achieved a recruitment rate of 69.6%[187]. For the future large-scale RCT, coaches and participants suggested using different methods for advertising the intervention, including social media platforms, physicians, and relatives. Coaches emphasised that the majority of participants were referred by their doctors because they thought this was the most suitable and trustworthy recruiting strategy. Moreover, they emphasised the need to keep recruiters, such as doctors, fully aware of the intervention's nature and content in order to effectively promote the programme, given the intervention's status as a new unique method in the Saudi context. They also stressed how important it is for patients who wish to enrol to understand the intervention approach during the recruiting stage. Participants and coaches agreed that a brief video explaining the intervention should be made and shared in order to communicate the message effectively, ensure that there are no inconsistencies in how the intervention is explained to

potential participants, and save time. As a result, participants may not need to attend an initial orientation to learn about the intervention.

Considering that health coaching was newly applied to an older cohort and implemented amid COVID-19 restrictions, the retention rate exceeded expectations, reaching 97%. All participants who started the intervention continued until the intervention endpoint. The participant who dropped out of the research before the first session was contacted to find out if there were any intervention-related causes that led to withdrawal; however, the reason was a family matter rather than related to the intervention offered. It is worth mentioning the participants' appreciation for the intervention as they view it as an opportunity that should be given to committed people who intend to make changes. As compared to the relevant literature, this result indicated a higher retention rate compared to 83.6% in the study by a similar intervention [186], 87% in the study by Basak C & Schou (2013)[185], and 90% in the study by Cho et al. (2011)[187]. The high retention rate achieved in this trial indicated promise for a high retention rate in the larger-scale RCT, which is important given that dropout rates for digital health interventions are frequently higher than those for face-to-face interventions [188].

All health coaching sessions were successfully delivered with a high adherence rate exceeding the predetermined criteria (adherence rate 100%). Seventy-three sessions were delivered as previously scheduled, while only eleven sessions were rescheduled, most of which occurred at the intervention midterm (n=6), specifically the fourth session. The rescheduling happened at that specific time due to new COVID-19 restrictions, where some work remotely from home conflicts with other work, e.g., online classes for children in homes. As compared to a comparable intervention by Kim et al. (2015), which showed an adherence rate of 90.8%[186], this study's adherence rate was shown to be better. The quantitative and qualitative meta-inference integration showed how each method's findings strongly supported and confirmed each other. Many participants demonstrated a strong desire for more sessions as they hoped to

maintain the progress achieved. As a result, more sessions were suggested by both coaches and participants to be included in future RCT with a maximum of six months, with biweekly sessions during the first three months and monthly sessions during the last three months.

It was noticed that the flexibility health coaches used when rescheduling specific sessions (n=11) helped participants stay committed to sessions, but at the same time, it placed pressure on coaches to find a suitable time for such sessions. Despite the added load due to rescheduled sessions, health coaches believed that flexibility is crucial and should only be employed for a reasonable percentage of the overall sessions, such as between 10% and 15%. In the context of this study, the percentage of rescheduled sessions was 13%, which was a reasonable rate as described by coaches. It is crucial to highlight that health coaches participated in this study as volunteers while working full-time jobs; thus, flexibility would not be an issue if they were granted leave from their jobs and compensated as coaches in the intervention.

Different outcomes assessments were collected pre-and post-intervention, including semi-structured interviews, focus groups, questionnaires, and efficacy outcomes. The process of achieving data saturation was accomplished through focus groups and semi-structured interviews. This approach continued until no additional information was discovered, ensuring comprehensive and exhaustive data collection. [133]. Despite COVID-19 restrictions and the fact the intervention was not funded, the data collection process demonstrated high adherence from participants from both groups. All data was completed and collected at the planned time (100%). A previous health coaching study by DeJesus et al. (2012) reported a lower data collection rate of 63% of total participants[165]. Moreover, qualitative data showed no complaints from participants regarding how data was collected. In addition, the selected outcomes assessments, including HbA1C, blood pressure, BMI, weight, waist circumference, and questionnaires, seemed appropriate as coaches believed they were adequate to assess the efficacy of health coaching with T2DM patients. Therefore, no more outcomes are likely

needed in the future larger RCT. The overall findings from both methods hold promises for successful data collection in the future larger RCT as they were acceptable in this feasibility trial.

6.3 Intervention mechanism and participants' experience

As previously discussed (see Chapter 3), the COM-B model was selected to guide the intervention's design and content due to the current discrepancies in the literature's findings and their development. In addition, the BCTs taxonomy was used to operationalise the adapted curriculum by carrying out the intervention activities towards achieving the four target behaviours. The results of the current study showed that the COM-B model was helpful in guiding the content of the intervention and enhancing its overall effectiveness. Thus, the intervention's detailed curriculum helped health coaches to prepare and stay on track, delivering each session as planned. It also helped them address different barriers presented by participants by selecting different proposed BCTs to effectively use the time of each session. As it was the first time they used such a curriculum and especially the use of BCTs, they believed it was acceptable, useful, straightforward, and easy to use. Several BCTs were used throughout 84 coaching sessions. The result of the use of BCTs was consistent with the systematic review result reported that *1.1 Goal setting (Behaviour)* is the most used BCT, whereas *1.3 Goal setting (outcome)* and *1.7 Review outcome goal (s)* came as the second most frequently used BCTs. Other BCTs were found to be useful when used by coaches, including *8.7 Graded tasks, 5.5 Anticipated regrets, 5.3 Information about social and environmental consequences, 12.1 Restructuring the physical environment,* and *12.2 Restructuring the social environment.*

The systematic review showed that health coaching was delivered through face-to-face, telephone-based, and mobile-based remote patient monitoring/electronic assistance. Although

a combination of face-to-face and telephone-based methods was planned as these were the most popular ones in the review (n=7)—this study adjusted to use only telephone-based sessions due to COVID-19 restrictions. The systematic review suggests that no particular delivery method for health coaching showed significant benefits over others. Additionally, there was no link between better outcomes and a specific length of a coaching session. The result of this study emphasised the participants' and coaches' preference for the use of a combination of face-to-face and telephone-based in the future. Given the nature of coaching skills, which require actual presence and building trust, they believed that more face-to-face sessions, especially in the beginning, may result in even better results. Although the wider evidence base suggests digital health interventions tend to have a lower retention rate than those with face-to-face [188], the study's retention and adherence rates to telephone-based sessions were high, indicating that the future larger RCT with a combination of face-to-face and telephone-based holds promise for success. Using this combination to deliver the intervention may enhance participant retention, strengthen engagement, and foster a better relationship between health coaches and participants.

In addition, studies included in the review were varied in terms of intervention duration, with a median of six months. Given that this study was designed to last for three months, participants and coaches suggested a maximum of six months duration for the future larger RCT. The justification behind their suggestion of a six-month duration was to maintain the progress achieved and ensure new behaviours were sustained.

Adding to the quantitative findings that suggest positive change was achieved by participants as a result of the coaching intervention, qualitative findings suggest that this was achieved because of both the participants' and coaches' positive experiences and views regarding the design and content of the intervention. As health coaching emphasizes patient-centredness, participants were noted to take responsibility for developing and adopting various core skills

to self-manage their conditions. Among these skills, SMART goals, action plans, problem-solving, and reviewing outcome goals were frequently reported and used to achieve short- and long-term goals during different sessions. Qualitative data revealed that participants were capable of sourcing credible information on various topics, such as nutrition, which was noted to be a key difference between health coaching and usual care.

These qualitative results were consistent with the previous literature [17] [80], emphasising that patients could not have enough time to discuss their concerns during regular visits to doctors. This study revealed that the time participants spent with doctors was approximately 1-3 minutes shorter than the time described in the literature [80]. In fact, all interviewed participants were unsatisfied with their routine healthcare visits' outcomes.

In addition, the present study's findings supported the current literature, indicating that the client-centred approach seemed to address participants' concerns effectively [121]. Participants in this study have emphasised their need to be heard and given adequate time to discuss what concerns them instead of telling them what to do. For instance, one participant clarified that she would choose health coaching over usual care if asked to choose one for the aforementioned reasons. Another participant justified paying for private healthcare to have enough time to discuss her health concerns. All participants in the intervention group positively described their relationship with health coaches. Most participants described their interaction with health coaches as supportive, good listeners, helpful, accepting, encouraging, and non-judgmental. For example, one participant expressed how comfortable she was during and after each coaching session compared to her regular "frustrated" visits to her doctor.

Although feasibility studies are not formally powered to detect conclusive effects on intervention [189], this mixed feasibility study demonstrated the advantage of using health coaching with people with T2DM. The study's findings reported improvements in different

outcomes (n=5), favouring the health coaching group over the control group, including the primary outcome and the outcome most commonly used to assess the effectiveness of interventions for the management of T2DM, HbA1c. Clinically significant improvement was observed between the two groups, with decreased HbA1c in the health coaching group. The estimated effect size of the intervention was large (d= -0.93) compared to the current literature on the effect of health coaching with T2DM. The systematic review (see Chapter 3) showed the effect sizes of the included studies ranged from d= -0.05 to d=0.78. Our systematic review revealed that interventions with HbA1c as the primary outcome demonstrated better effectiveness than studies with other primary outcomes. This emphasizes the importance of aligning the primary outcome with the central goal of the intervention in a study. As a result, the glycaemic level was the primary outcome of this feasibility study, which showed a positive impact on participants' diabetes self-management. This is further supported by the qualitative findings, where participants expressed their satisfaction, which was linked to the reduction in HbA1c levels after the intervention. However, it is worth noting that some participants had other concerns, such as one individual who frequently complained about her blood pressure during coaching sessions, indicating that it was her priority over her diabetes management.

The recent observational study on the effectiveness of health coaching in SA supports our case for further RCT evidence[22]. It found a significant weight change over 12 weeks of health coaching, indicating preliminary support for the effectiveness of health coaching in the Saudi context. However, it did not address feasibility and acceptability, which our study was able to explore, thereby complementing the existing literature. The results of our RCT add significantly to the evidence to support the potential implementation of health coaching, if a larger trial confirms effectiveness, by demonstrating its feasibility and acceptability.

The study measured participants' confidence levels in performing tasks through a self-efficacy questionnaire. The results showed that the intervention group had higher improvements in

confidence compared to the control group. Additionally, the study found that self-care behaviours varied among participants, but most exceeded or met the guidelines set by the American Diabetes Association, especially in the intervention group.[190]. These preliminary findings, high retention rate and positive outcomes in our feasibility RCT further indicate that a more extensive, fully powered RCT would be beneficial for confirming the effectiveness of health coaching in SA, thereby substantiating the observational study's findings[22].

6.4 Sample size estimation for the main RCT

The systematic review (see Chapter 3) revealed that studies assessing the effectiveness of health coaching varied widely in sample size, ranging from 50 to 574 participants[149]. Notably, five studies[121 187 191-193] had relatively small sample sizes, with a maximum of 71 participants, consisting of 50, 53,56, 62, and 71 participants, respectively. Another similar study to our study has recruited a total of 114 participants[180].

Determining the sample size for a future larger trial requires careful consideration of several factors. Based on the findings of this study, a small sample size might be sufficient to evaluate the effectiveness of health coaching in SA. Nevertheless, it is essential to cautiously interpret the feasibility study and consider various factors to adequately inform the main trial. Estimating the sample size for the future larger RCT study involves taking multiple factors into account.

One such factor is the effect size. Our pilot study observed an effect size of -0.93, while the literature suggests a mean difference of 0.5. This difference might be more appropriate if the larger trial's effect size is expected to align with previous research findings. The decision between using the observed effect size of -0.93 and the suggested mean difference of 0.5 depends on the expectations and objectives of the main trial.

There are several reasons why a larger sample size might be necessary for the larger RCT. If the effect size in the larger trial is expected to be smaller, especially when recruitment and intervention delivery resemble "real-world" conditions; a larger sample size would be warranted. Furthermore, if subgroup analyses are planned to investigate effect sizes or benefits in different settings or patient groups, a larger sample size might be needed. This consideration is particularly important if the intervention is not affordable for every patient, and there is a need to identify patients who are most likely to benefit from the coaching programme.

6.5 Acceptability and usability of the intervention

Because this feasibility study was the first health coaching study that used the COM-B model and BCTs taxonomy and was newly applied to the context of SA, it was important to collect comprehensive data to inform the development and delivery of a health coaching intervention to be provided in a future definitive trial. Therefore, the acceptability and usability of the intervention of this study were measured through qualitative and quantitative methods to provide a rich understanding of to what extent the intervention fit into the Saudi context, and its implementation was acceptable to the patients. The study demonstrated that most participants found the intervention implementation and procedures acceptable and easy to use. Qualitative results through focus groups, interviews, and questionnaires revealed no issues related to the acceptability of intervention methods were raised.

Although health coaches were generally happy with the intervention implementation, they had some concerns. As previously discussed, they had worked in the intervention as volunteers indicating they did not work full-time in this study, so they had experienced pressure with the workload and conflicts with their main duties, especially when some participants requested rescheduling sessions. In addition, as an unfunded study, health coaches expressed difficulty

finding a private and quiet place to carry out some coaching sessions. They have emphasised taking these concerns into account when preparing for the future larger RCT.

It is worth mentioning that substantial societal shifts and developments are currently taking place in SA following the Saudi Vision 2030. Although the strategy has been in place for eight years since it was released in 2016, improvements have had a variable impact on different aspects of Saudi society. The current societal acceptance of new and radical social changes may be due to the majority of the Saudi population being under 25 [27]. Different Saudi social norms have been considered for years as one of the main barriers to various issues, including people's health conditions. Social norms and attitudes have a significant impact on controlling diabetes, according to T2DM patients in SA [80 86 89]. Social life in SA may negatively discourage people with T2DM from adopting healthy lifestyles [92]. Despite the fact that numerous studies have demonstrated that barriers to adopting a healthy lifestyle for T2DM in SA are closely related to the social and environmental context structure [80 86 89], the results of this study showed those barriers no longer prevent some people from making positive changes. Qualitative findings indicated that the current generations are more open to recent changes, including adopting healthy behaviours. For example, it was not common in the past, especially for women, to exercise in public because of social norms; however, the findings of this study showed that participants, both men and women, do outdoor activities together in public recreation centres like parks. Participants have reported that many people are now doing different physical activities because of the widespread recreation centres, which was part of the Saudi Vision 2030. This suggests the possibility of acceptance for a large-scale RCT, given that the key recognised barriers reported in the literature are not regarded as a challenge as in the past.

Even though recent changes in Saudi Arabian society have created a more favourable environment for adopting healthier lifestyles, like better nutrition and more exercise, we must

examine the full scope and impact of these shifts. Claiming that all obstacles to healthy living have been completely eliminated would be unrealistic. Additionally, the benefits of these changes may not be evenly distributed across various economic groups, potentially worsening existing disparities in health. For instance, wealthier segments of the population might more readily afford healthier food options or have easier access to exercise facilities. Also, the cost and payment models of the proposed intervention could contribute to inequality by limiting access for less affluent individuals. As such, it's vital to approach these societal changes with a critical lens, considering their impact not just on the general population but on various subgroups as well.

6.6 Satisfaction with the intervention

The reported satisfaction rate exceeded expectations, despite facing various challenges. The intervention was implemented amidst the challenging circumstances of the COVID-19 pandemic, which imposed various limitations and constraints. Furthermore, it was the first time this approach was used in SA, and the study participants were older, potentially making them resistant to change. Typically, these factors would contribute to lower satisfaction rates; however, the satisfaction rate was unexpectedly high. Even the health coaches did not anticipate such positive outcomes.

However, all the qualitative data collected demonstrated a high level of satisfaction with the intervention. All interviewed participants expressed that they were happy and satisfied with the intervention. The quantitative data results, on the other hand, also suggested that participants were highly satisfied. All participants in the intervention group (n=14) answered "Yes" when they were asked if they would recommend the intervention to others. Most of them (n=13) responded with “Yes” when they were asked if the intervention had met their expectations. The findings of focus groups and interviews revealed that some participants strongly desired health

coaches to play a role within the provided healthcare services. They felt that doing so would help reduce the high demand for healthcare services and improve health outcomes. This idea was consistent with the stated benefits of offering health coaching as a service in the healthcare system in the current literature. Health coaching may be a practical solution with several advantages since health coaches can help relieve the time and burden on healthcare practitioners [194]. Furthermore, this recommendation revealed how satisfied participants were with the intervention.

6.7 Improvement opportunities in the future definitive RCT

To ensure future applicability and boost the likelihood of successful implementation, participants' and coaches' viewpoints and feedback on the study methods for recruitment and data collection as well as the intervention delivery, are essential components of feasibility studies [135]. Health coaches and participants have provided various helpful recommendations and feedback to improve the implementation of a future definitive RCT. Although the median duration of studies included in the systematic review was six months, the findings of the review showed no advantage of specific intervention duration. Hence, this feasibility study sought to explore participants' specific intervention duration preference for the future larger RCT. Both health coaches and participants agreed that increasing the intervention period to a maximum of six months with more face-to-face sessions would result in more meaningful sessions and better outcomes.

As the health coaches' background was in health education, a need for involving experts from other fields, namely a diabetes doctor and a nutritionist, for quick consultations was identified by health coaches. In addition, they recommended having frequent meetings with each other throughout the intervention period to assist each other in addressing challenges related to the intervention implementation.

Since the feasibility study required a small sample size, recruiting the necessary number of participants at this stage was not difficult. Nonetheless, health coaches proposed giving incentives to promote participation in the intervention for better recruiting outcomes. Incentives can be financial in some instances, but they also advised providing other forms of incentives by offering some services, such as quick access to physicians or medical facilities. Finally, a short video was suggested to be created and distributed to prospective participants during the recruiting process to clarify the concept of health coaching, save session time, and minimise drop-out rates.

While the qualitative feedback provided valuable suggestions for refining the intervention, it is essential to consider the economic and practical implications of each recommendation. Extending the duration or increasing the number of sessions, for example, will likely lead to higher operational costs. Introducing more clinical involvement could also add financial and logistical complexity. Shifting to face-to-face coaching raises both cost and accessibility concerns, and offering financial incentives could not only inflate the budget but also bring ethical questions into play. Each of these modifications carries implications for the intervention's cost-effectiveness and may warrant further feasibility testing. As much as it is tempting to act on all suggestions, implementing them could complicate not just the trial phase but also future scaling and implementation within the healthcare system. Therefore, it is critical to balance the desire for improvement with the need for economic and logistical viability.

CHAPTER 7: Thesis Conclusion and Recommendations

7.1 Introduction

This chapter provides a comprehensive summary of the study's main findings, along with its broader implications and lessons learned from the thesis. The chapter begins by highlighting the study's contribution to current knowledge, followed by its implications for future trial methods, development, policy, practice, and future research. Additionally, a section highlights the impact of the COVID-19 pandemic on the research. The study's strengths and limitations are discussed, and the chapter ends with a plan for disseminating the research and a general conclusion.

7.2 Original contribution to knowledge

While there has been a recent observational study investigating the effectiveness of health coaching for weight management in SA[22], to the best of my knowledge, this is the first study that specifically seeks to explore the feasibility and acceptability of conducting a full-scale health coaching intervention to address T2DM in the SA context. This distinction is particularly important given that the effectiveness of an intervention not only relies on its efficacy but also on its practical applicability and acceptance within a specific cultural setting. In addition to being the first study of its kind, this one thoroughly examined the feasibility and acceptability of health coaching in the Saudi context using a mixed methods approach to explore in-depth information from both quantitative and qualitative techniques. By integrating both methods, this study provided a better understanding of health coaching feasibility and acceptability in the real world from a pragmatic standpoint. As a result, the study's findings helped identify key uncertainties prior to conducting a more definitive RCT, which would effectively help to save

time, effort, and cost. By identifying key uncertainties, the findings will help to inform the research development process of the future full-scale intervention.

Given the existing gap and inconsistent reported outcomes of health coaching programmes in the literature, this feasibility study used unique content based on the findings of the systematic review and meta-analysis (see Chapter 3). The findings from the review add value to the current literature, which also helped inform the implementation of this feasibility study. The review demonstrated unique findings given that utilising HbA1c as the primary intervention outcome would improve effectiveness and that neither a particular intervention length nor a particular mode of intervention delivery was anticipated to improve intervention efficacy.

Furthermore, this study followed a precise structure based on the COM-B model to identify and address reported barriers to diabetes self-management of people with T2DM in SA. In order to systematically direct the intervention activities, the COM-B model was used for the first time with health coaching. Moreover, this was the first study utilising the BCTs taxonomy to operationalize actions involving active ingredients in a health coaching intervention. This study is unique because it is the first to use specific 'active ingredients' techniques (BCTs) that align with the underlying theories of the intervention. This could be helpful for health coaching intervention designers looking to identify effective BCTs for future replications. The study's findings could also encourage the adoption of other behaviour change interventions in SA. Given that this intervention aimed to address health-related behaviours, particularly diet and physical activity, the study's novel findings contribute to the current literature and may inform research on health coaching for T2DM and similar interventions for both T2DM and other chronic conditions, specifically in the context of SA.

Due to the significant socioeconomic shifts SA has undergone since the release of Vision 2030; as a result, the study revealed a potential changing context in terms of social attitudes. The

study was conducted during the country's significant transition, where many rules and social norms started to change. As it was commonly reported by several studies that the Saudi culture and social norms were identified as barriers preventing people from adopting health behaviours, this study showed how the society is hugely changing and started accepting and adopting new positive habits. For example, different studies found that women had limited opportunities to participate in public activities like walking or hiking due to social norms. However, this study found that women did different public physical activities as they acknowledged the huge societal change. The implications of Vision 2030 have not only affected social aspects but have also been reflected in the environment, where many public parks and leisure centres are spread out in the country as a part of one of the Vision 2030 strategies, "toward an active community". As a result, contrary to what has been widely stated in the past literature, additional opportunities are now available. Therefore, this study's findings provide new evidence for changes that might favour public support for these changes.

7.3 Implications for Trial Methods

The implications of this feasibility study provide helpful guidance for designing and implementing future health coaching trials in SA. Effective recruitment strategies were identified, indicating that secondary and primary care centres are more effective for participant recruitment compared to larger, busier tertiary hospitals. It was also found that involving physicians in recruitment could leverage their trusted relationship with potential participants, enhancing recruitment outcomes. Furthermore, the potential of social media platforms for participant recruitment was underscored, and incentives such as complimentary medical services or financial rewards were suggested to further boost participation.

An interesting finding was that participants preferred a more extended duration for the intervention and favoured a mixed-mode delivery of coaching, encompassing both face-to-face

and phone-based sessions. These initial insights could help the design of future chronic disease management interventions in SA, emphasising the importance of considering participants' preferences. Collectively, these implications offer important guidelines for enhancing the methodologies of future health coaching trials in managing T2DM and potentially other chronic diseases within the Saudi context.

7.4 Implications of the feasibility study for the development of health coaching for patients with chronic disease, including diabetes

While a recent observational study has begun to explore the benefits of a patient-centred approach in the Saudi healthcare system[22], this research is the first feasibility study in SA to specifically employ health coaching for the management of T2DM. Our study not only explored the effectiveness of the approach but also thoroughly assessed its feasibility and acceptability, revealing high satisfaction rates among participants. This outcome suggests that utilizing a patient-centred approach such as health coaching could be beneficial not only for managing T2DM but also potentially for treating other chronic diseases in the Saudi context. Participants greatly appreciated the personalised nature of the intervention, underlining the broad potential applicability of this style of health coaching for enhancing patient experiences and promoting treatment adherence in the realm of chronic disease management.

As another significant implication of this feasibility study, it provided a detailed and comprehensive curriculum of the intervention and its activities to overcome the challenges of imprecision and insufficiency often seen in health coaching programmes. This curriculum provides a solid foundation that could greatly facilitate the development of future interventions for managing chronic diseases, including the creation of similar health coaching programmes.

The COM-B model and BCTs played an integral role in the successful execution of this feasibility study, demonstrating their potential in effective behaviour change interventions.

This underscores the importance of incorporating such frameworks in the design of future chronic disease management programmes.

The feasibility study underscored the necessity for comprehensive training for health coaches, administrative support, and adequate resources. These elements are critical to creating optimal working conditions for health coaches, ensuring the overall quality of the intervention. This feasibility study has provided vital insights and direction for the expansion of health coaching in managing chronic diseases in SA. It has emphasized the necessity of context-specific adaptations for effective implementation within the local healthcare system.

7.5 Implication for policy and practice

As previously highlighted (see Chapter 1), traditional Saudi healthcare approaches rely mostly on education as a major component in addressing T2DM conditions. Nonetheless, the overall impact of diabetes education initiatives was suboptimal [65]. Recently, the MoH has realised the value of adopting the new approach of behaviour-based rather than education-based programmemes[195]. Health coaching is a new approach recently included in the MoH plan to be applied soon. While health coaching is newly included in the MoH's upcoming plans, this study serves as the first to assess the feasibility and acceptability of this approach in the Saudi context.

A recent observational study[22], alongside the current study, reinforces the potential utility of health coaching for managing chronic conditions, providing additional support for the MoH's planned transition to behaviour-based healthcare [196]. Our findings demonstrate that a larger-scale RCT is both feasible and acceptable in Saudi Arabia. Although feasibility studies are not designed to definitively assess efficacy, preliminary improvements in outcomes—most notably HbA1c levels—were observed. Given these encouraging results and the current shifts in Saudi society and healthcare, the MoH may find this study's insights valuable for refining and expanding its new behaviour change-focused approach.

The study's findings may be helpful for current T2DM healthcare practices in SA. The results of this study indicated that using a client-centred approach like health coaching was helpful in enabling patients to develop related core skills for better self-management over diabetes. Results revealed that patients preferred individualized programmes to address different causes of the condition that each patient has, as there is no one-size-fits-all. In addition, it was clear how vital giving enough time to listen and understand each patient's problem was, as most of the participants in this study had difficulty finding enough time with their doctors. As a result, when participants were asked for their suggestions, the majority stated that the programme should be expanded and that health coaching should be a component of the healthcare services they receive. Therefore, this study's results supported the new healthcare transition the MoH intends to undertake, emphasising the significance of tailored client-centred based programmes to address some chronic diseases, including T2DM.

The research's implications extend beyond the Saudi context and could impact clinical practice in various settings. For instance, before the systematic review's findings were published, a West London NHS Trust health practitioner contacted me and showed interest in the findings through email (see Appendix 14). The trust intends to introduce a comparable service and recognises the significance of incorporating research-based insights into its work.

The importance of turning academic findings into practical advice for healthcare providers is underscored by this example. In addition, it showcases the benefits of partnerships between healthcare professionals and researchers in improving health coaching interventions for individuals with T2DM.

The present study sought to provide significant information to determine if a larger health coaching intervention was feasible and acceptable. It is hoped that the results of this study will help to inform the development of future trials as well as the current literature. As an early

effort to explore patient-centred approaches like health coaching in the Saudi context, this study is expected to add to the growing body of evidence that supports self-management interventions. The findings may offer useful insights for healthcare policies and practices that are increasingly considering patient-centric strategies.

5.6 General recommendations for future research and the definitive trial

The following suggestions are based on this feasibility study's findings for the future trial to increase its likelihood of success.

- More research is needed to explore and evaluate the social and environmental impacts following the Saudi Vision 2030 on the lifestyle of people with T2DM.
- Considering the importance of social media in the Saudi context, it is recommended that the future larger RCT be advertised through both traditional and modern approaches, such as Twitter, WhatsApp, and Snapchat, as well as leaflets, for better recruitment outcomes.
- Given the nature of the health coaching approach, the participants' education level is crucial; recruiting people with a minimum primary education is recommended.
- It is recommended that the future intervention duration last for six months and use a combination of delivery modes (face-to-face and phone-based).
- As the systematic review reported (see Chapter 3), using HbA1c as the primary outcome is associated with bigger effect sizes, so it is recommended that HbA1c be the intervention's primary outcome in the future trial.
- The curriculum used in this study was found to be feasible and acceptable, so it is recommended to be used for the future larger RCT.

7.7 Strengths and limitations of the study

A strength of this thesis was the use of the BCW framework as a systematic guide. The framework helped us understand the problem of T2DM in the context of SA by analysing the previous literature. Proper diagnosis of the targeted problem, including possible barriers and facilitators, is important to the methodical roadmap, which begins with detecting the real issue and ends with specific target behaviours to achieve the intended goals [88]. Using the COM-B model, a narrative review was carried out to identify facilitators and barriers to controlling T2DM.

In addition, a knowledge gap was identified (inconsistent effectiveness reporting for health coaching), so a systematic review and meta-analysis was conducted to address the gap. The review revealed novel findings that would contribute to the existing literature. Moreover, the review findings effectively helped inform the feasibility study's implementation. As a result, and to the best of our knowledge, the feasibility study was the first health coaching intervention guided by the BCW and COM-B model framework and the BCTs taxonomy. Moreover, it was the first feasibility study to analyse every health coaching session (n=84) and code every BCT that was applied during those sessions (see Chapter 5). Consequently, the description of the intervention was clearly specified and outlined to evaluate the intervention effectively.

This study included progression criteria, as recommended by the CONSORT 2010 statement, to assist in making the decision on how to proceed to the definitive larger trial [147]. Despite the importance of incorporating predetermined criteria into the protocol of feasibility studies, only 45 of the 227 studies included in a recent systematic review reported progression criteria [197].

The study findings, including the standard deviation, effect size, and retention rate, helped to inform the future main trial by estimating the sample size needed to detect a meaningful clinical difference in HbA1c. This would lead the future intervention to recruit an appropriate number

of participants with enough statistical power to assess the effectiveness of health coaching to improve the self-management of patients with T2DM.

It was the first health coaching intervention that used both questionnaires in one study: Summary of Diabetes Self Care Activity and Self-efficacy Scale for Diabetes scale. The Summary of Diabetes Self-Care Activity questionnaire was only used in two previous studies [182] [198], whereas the Self-efficacy Scale for Diabetes scale was only used in one study [186]. This study used the combination of the two scales to better understand the effect of health coaching on participants' diabetes self-care activities and their self-efficacy to do those activities pre-and post-intervention. The Likert-scale Satisfaction Questionnaire was used for the first time outside of its developers in a health coaching intervention. Moreover, it was the first time the questionnaire was translated into Arabic and implemented in an Arabic setting. It is important to note that the questionnaire that was translated showed strong reliability in this study.

From a pragmatic standpoint and real-world research, this study used a mixed methods approach, which helped to provide further explanations to better understand the feasibility and acceptability by gathering information from different methods. In healthcare research, the mixed methods approach is commonly employed to gather more information and identify and address complicated issues [199]. As exploratory research, relying on one method would limit the efficacy of the judgment on whether to proceed to the larger trial or not. The use of a mixed methods approach in this study allowed us to examine more data in a single study, producing more information than if we had just used one method [200]. Furthermore, different key findings were produced as a result of using the convergent design by integrating data from quantitative and quantitative approaches to validate the independent findings of each method.

In addition, by integrating the data from each method, we were able to assess and improve the validity and reliability of the study's findings, which would not have been feasible when

utilising only one method. In terms of the validity of the study's findings, the intervention activities, such as the health coaching sessions, were not carried out by the researcher. Semi-structured interviews and focus groups, among other assessment methods, were carried out by the researcher. This may have limited the extent to which a desire to maintain a good relationship with the interviewer and social acceptability bias influenced responses.

Although this feasibility RCT provided insightful information on the feasibility and acceptability of implementing health coaching in SA, it is important to note that this study also has limitations. First, the study was designed to explore the feasibility of health coaching rather than its actual effectiveness. Therefore, while the results are encouraging, they are preliminary and should not be considered conclusive evidence of the intervention's effectiveness. Another limitation of this feasibility study is its small sample size. While the research indicates that health coaching is possible on a limited scale, these findings cannot be assumed to apply in a broader context or among larger groups. Given that this feasibility study was carried out in a specific setting and population, the generalizability of the study's results may be limited. It should be noted that the intervention sample was recruited from a public hospital, which may not be applicable to primary care settings. Randomising participants, while useful for reducing allocation bias, does not fully mitigate other forms of bias that could affect the study's outcomes. The potential for selection bias remains significant and could appear in multiple forms. For example, non-response bias could occur if the people who agreed to join the study differ in specific characteristics from those who chose not to participate. Similarly, volunteer bias might occur when the people who volunteered exhibit specific traits that do not accurately represent the broader population. Additionally, the method used to select participants and set eligibility criteria could introduce sampling bias. These biases could impact the interpretation and application of the study's findings.

Another significant constraint was the study's lack of external funding. The health coaches' recruitment, training, and support were solely managed and financed by the researcher. This lack of financial resources had real-world implications: the initial team of coaches had to withdraw after seven weeks of training, requiring a new team to be formed and trained. While this second team successfully completed the intervention, their training and support would likely have been more robust in a funded trial. Lastly, the intervention was not administered in the same manner as planned for the future comprehensive study; for example, I employed volunteer health coaches, which may not be the case in the future larger trial.

These limitations are critical considerations for future research, and they underscore the need for a well-funded, large-scale trial to more definitively assess the efficacy and applicability of health coaching in different settings within SA.

7.8 Implications of the COVID-19 pandemic on this research

This PhD programme started on November 1st, 2019, two months before coronavirus was detected in China in December 2019. The WHO declared the coronavirus outbreak a pandemic on March 11th, 2020 [201]. As the virus rapidly spread, this led to many changes, affecting people's daily lives. As a student who spent the majority of my PhD time during this pandemic, from the first wave, which began in February 2020, to the fourth wave, which began in December 2021, the implications of the pandemic on my PhD journey are worth mentioning here.

As the situation got worse, several restrictions were imposed. Following those restrictions, supervision meetings with supervisors were only online, which was against my preference. In addition, there was limited access to the university’s facilities, including PhD student offices and the university library. Consequently, the opportunity to have helpful discussions with my

colleagues was made difficult during the lockdowns. Thus, working from home was the new normal condition that I had to adopt during the pandemic. In my case, it was very challenging working from home for many reasons, such as the limited technical resources. Furthermore, there was personal and family stress during the lockdowns due to the long time spent at home and the limited opportunities to do outdoor activities, especially for the children.

In the course of research implementation, I needed to conduct the intervention in SA while the second wave of the pandemic had just begun. The Saudi government's rapid response to the COVID-19 pandemic included suspending all flights into and out of the country, imposing a general national curfew, and restricting daily travel. Many public places and services, including restaurants, shops, and gyms, were also shut down. Moreover, hospitals took strict precautions to contain the virus's spread, leading to limited hospital access for people with T2DM.

This situation presented challenges for the research team since we needed to carry out the intervention in a hospital setting. Initially, we received approval from KFMC to conduct the intervention, but one week later, the diabetes department converted all clinics to virtual clinics, making participant recruitment challenging and complicated. The department suggested that we change the intervention's setting to another public hospital where participants could access the hospital. However, changing the intervention's setting took six weeks due to the pandemic's implications. Furthermore, as a result of KFMC's new regulations, the research team, which consisted of two health coaches who had previously finished the intervention curriculum training, was given extra duties from the hospital, causing them to withdraw from this project. As a result, it was an extremely stressful time, given that no funding was available to hire new health coaches. Fortunately, three new coaches agreed to take part in the intervention, so they undertook further training for an additional six weeks. The COVID-19 implications, which were beyond my control, were quite stressful for me as the researcher to maintain positive progress, especially prior to the intervention recruitment phase.

The effects of the COVID-19 pandemic extended beyond the initial intervention stage and affected certain aspects of intervention procedures. According to the intervention protocol, the first and last coaching sessions were supposed to be face-to-face; however, this was not the case; therefore, we conducted those sessions virtually. Additionally, because SA's whole educational system has gone virtual, some participants were unable to commit to the scheduled coaching sessions due to scheduling conflicts with their children's classes. Moreover, COVID-19 restrictions forced us to conduct all interviews and focus groups online using an online platform, which limited the opportunity for the researcher to have a meaningful face-to-face discussion with participants as I had originally planned.

7.9 Planned dissemination

The study's findings will be presented at the 9th Conference of the Centre for Behaviour Change (CBC), which will take place at University College London, as well as at the UK Public Health Science Conference, London, November 2023. I have published two papers in scholarly journals, namely a systematic review and a meta-analysis in the BMC Public Health Journal (see Chapter 3) and a paper detailing the protocol of a health coaching feasibility study in the International Journal of Environmental Research and Public Health (IJERPH) (see Chapter 4). I was the corresponding and first author for both publications. A manuscript outlining the study's findings is currently under review by the co-authors and will be submitted to the BMJ open journal soon. The MoH in SA will also receive a copy of the findings as per their request.

7.10 Reflexive

Maintaining reflexive awareness in research is crucial, especially when navigating a mixed-methods study like mine, which focuses on diabetes healthcare. Reflexivity involves critically reflecting on one's role as a researcher and the research process[202]. These reflections are

particularly essential in thematic analysis, where the reflexive approach fully integrates the values of the qualitative paradigm into the research practice[202].

My background in health coaching and a master's degree in health promotion from the U.S. shape my perspective. This background has the potential to introduce a bias towards favouring health coaching. However, I have consistently remained reflexively aware, ensuring a balanced data collection and analysis approach. Braun and Clarke (2021), emphasize the importance of acknowledging the researcher's subjective and situated role in shaping the study[202].

One of the significant challenges of qualitative research, as noted by Creswell (2016), is the inherent risk of varied interpretations when analysing and coding qualitative data[140]. It is imperative that I maintain a reflexive stance, continually reflecting on how my biases, experiences, and perspectives might influence the study and its participants[202]. Green and Thorogood (2018), highlight the dichotomy of emic (insider) and etic (outsider) perspectives in qualitative research[203]. The emic perspective is rooted in familiarity, where a researcher, being part of the culture under study, brings an intimate understanding of expressions, sentiments, and communication. This resonates with my position as a Saudi researcher studying my community, where I possess a unique insider perspective, especially concerning cultural nuances. This insider's view could, however, have led participants to be less expressive, presuming I inherently understood their contexts.

On the other hand, my education in the U.S. provided me with an etic perspective—an objective viewpoint uncoloured by pre-existing beliefs or biases. This unique position of being both an 'insider' and an 'outsider' enabled me to formulate culturally relevant questions while also critically assessing the current state of diabetes healthcare in Saudi Arabia from a more analytical standpoint.

Creswell (2016) further emphasizes the importance of a reflexivity statement, which includes the researcher's history, its potential influence on data interpretation, and the anticipated reactions from both participants and the broader readership to the study's findings[140]. In light of this, I reflect on how my background in health coaching, international education, and the combination of emic and etic perspectives have shaped my interpretation of the data, aligning it with reflexive thematic analysis[202].

Moreover, my supervisors have played a vital role in ensuring objectivity. Their diverse experiences serve as a safeguard against any unintentional biases, especially during the data analysis phase. Finally, reflexivity remains a cornerstone of this study. The influences of my diverse background and education are recognized, harnessed, and carefully accounted for to enrich the research's integrity and depth.

7.11 Conclusion

This thesis is a mixed methods feasibility RCT that aimed to evaluate the feasibility and acceptability of implementing a health coaching approach for individuals with T2DM in SA. The integration of qualitative and quantitative findings resulted in positive outcomes, providing strong support for conducting a larger RCT to further investigate the effectiveness of health coaching in improving diabetes self-management among individuals with T2DM in SA. Furthermore, this study offers valuable insights that can guide future trials, especially regarding the incorporation of the COM-B model and BCTs taxonomy into the health coaching approach. Future research should focus on exploring the social and environmental impacts of Vision 2030, the national vision of SA, on diabetes self-management. By examining the contextual factors that may influence the implementation and outcomes of health coaching interventions for diabetes management in SA, such research would contribute to a deeper understanding of the subject and help inform future strategies to improve diabetes care in the country.

References

1. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implementation Science* 2011;6(1):42-42. doi: 10.1186/1748-5908-6-42
2. Schulz KF, Altman DG, Moher D. CONSORT 2010 Statement: Updated guidelines for reporting parallel group randomised trials. *BMJ (Online)* 2010;340(7748):698-702. doi: 10.1136/bmj.c332
3. Alqurashi KA, Aljabri KS, Bokhari SA. Prevalence of diabetes mellitus in a Saudi community. *Annals of Saudi Medicine* 2011;31(1):19-23. doi: 10.4103/0256-4947.75773
4. Hill B, Richardson B, Skouteris H. Do we know how to design effective health coaching interventions: A systematic review of the state of the literature. *American Journal of Health Promotion* 2015;29(5):e158-e68. doi: 10.4278/ajhp.130510-LIT-238
5. Organization WH. Global report on diabetes: executive summary: World Health Organization, 2016.
6. Noncommunicable diseases: World Health Organization; 2016 [Available from: https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases accessed 23 May 2020 2020.
7. Organization WH. Integrated chronic disease prevention and control: World Health Organization; 2016 [Available from: www.who.int/chp/about/integrated_cd/en/ accessed 13 Aprile 2020 2020.
8. Colosia AD, Palencia R, Khan S. Prevalence of hypertension and obesity in patients with type 2 diabetes mellitus in observational studies: A systematic literature review. *Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy* 2013;6:327-38. doi: 10.2147/DMSO.S51325
9. Al-Hazzaa HM. The public health burden of physical inactivity in saudi arabia. *Journal of family & community medicine* 2004;11(2):45-51.
10. Prevention CfDCa. Type 2 Diabetes: Centers for Disease Control and Prevention; 2020 [Available from: https://www.cdc.gov/diabetes/basics/type2.html accessed 3 June 2020 2020.
11. Bank W. New World Bank country classifications by income level: World Bank; 2022 [Available from: https://blogs.worldbank.org/opendata/new-world-bank-country-classifications-income-level-2022-2023 accessed 5 Feb 2022 2022.
12. International Diabetes F. Daibetes - Facts & figures IDF2015 [Available from: https://www.idf.org/aboutdiabetes/what-is-diabetes/facts-figures.html accessed 17 June 2020 2020.
13. Alqahtani M, Almutairi FE, Albasseet AO, et al. Knowledge, Attitude, and Practice of Diabetes Mellitus Among the Saudi Population in Riyadh, Saudi Arabia: A Quantitative Study. *Cureus* 2020 doi: 10.7759/cureus.6601
14. Al-Shahrani A, Al-Khaldi Y. Experience of the health promotion clinics in Aseer region, Saudi Arabia. *Journal of Family and Community Medicine* 2011;18(3):130-30. doi: 10.4103/2230-8229.90012
15. Azab AS. Glycemic control among diabetic patients. *Saudi Medical Journal* 2001;22(5):407-09.
16. Al-Hazzaa HM. Physical inactivity in Saudi Arabia revisited: A systematic review of inactivity prevalence and perceived barriers to active living. *International journal of health sciences* 2018;12(6):50-64.
17. Brox E, Fernandez-Luque L, Tøllefsen T, et al. The Impact of Health Education Transmitted Via Social Media or Text Messaging on Adolescent and Young Adult Risky Sexual Behavior. *Journal of the American Dietetic Association* 2013;18(3):158-62. doi: 10.1016/j.jada.2010.03.021
18. Wroth SW. Health Coaching Bridges Gaps in Patient Care. *Alternative and Complementary Therapies* 2015;21(4):157-59. doi: 10.1089/act.2015.29009.sww
19. Self-management interventions for chronic illness 2004. Lancet.
20. Trikkalinou A, Papazafiropoulou AK, Melidonis A. Type 2 diabetes and quality of life. *World Journal of Diabetes* 2017;8(4):120-20. doi: 10.4239/wjd.v8.i4.120

21. Wolever RQ, Simmons LA, Sforzo GA, et al. A Systematic Review of the Literature on Health and Wellness Coaching: Defining a Key Behavioral Intervention in Healthcare. *Global Advances in Health and Medicine* 2013;2(4):38-57. doi: 10.7453/gahmj.2013.042
22. Aldhamin RA, Al-Ghareeb G, Al Saif A, et al. Health Coaching for Weight Loss Among Overweight and Obese Individuals in Saudi Arabia: A Retrospective Analysis. *Cureus* 2023;15(7)
23. Pirbaglou M, Katz J, Motamed M, et al. Personal Health Coaching as a Type 2 Diabetes Mellitus Self-Management Strategy: A Systematic Review and Meta-Analysis of Randomized Controlled Trials: SAGE Publications Inc., 2018:1613-26.
24. GAS. Chapter 03: Health: General Authority for Statistics; 2019 [Available from: https://www.stats.gov.sa/en/1009 accessed 7 Feb 2020 2020.
25. Block RC, Dozier AM, Hazel-Fernandez L, et al. An epidemiologic transition of cardiovascular disease risk in Carriacou and Petite Martinique, Grenada: The Grenada heart project, 2005-2007. *Preventing Chronic Disease* 2012;9(4) doi: 10.5888/pcd9.110167
26. Hijab N. Regional Bureau for Arab States United Nations Development Programme Women Are Citizens Too: The Laws of the State, the Lives of Women.
27. KSA. Saudi Vision 2030: Kingdom of Saudi Arabia; 2016 [Available from: vision2030.gov.sa/download/file/fid/417 accessed 11 May 2020 2020.
28. MoH. National Center for Disease Prevention initiative Ministry of Health; 2017 [Available from: https://www.moh.gov.sa/Ministry/MediaCenter/News/Pages/News-2017-04-28-001.aspx2020.
29. GEOSA. Official Map of the Kingdom of Saudi Arabia: General Authority for Survey and Geospatial Information; 2017 [Available from: https://gasgi.gov.sa/En/Products/PublicMaps/Pages/General-Map-of-the-KSA(1-10,000,000).aspx accessed 8 Dec 2019 2019.
30. Organization WH. Noncommunicable diseases: World Health Organization; 2016 [Available from: https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases accessed 23 May 2020 2020.
31. Association AD. Diagnosis and classification of diabetes mellitus: ADA, 2010:S62-S62.
32. Health MO. Chronic Disease (Diabetes) Ministry Of Health: MoH; 2020 [Available from: https://www.moh.gov.sa/en/awarenessplateform/ChronicDisease/Pages/Diabetes.aspx2020.
33. Al-Rubeaan K. National surveillance for type 1, type 2 diabetes and prediabetes among children and adolescents: A population-based study (SAUDI-DM). *Journal of Epidemiology and Community Health* 2015;69(11):1045-51. doi: 10.1136/jech-2015-205710
34. Alwin Robert A, Abdulaziz Al Dawish M, Braham R, et al. Type 2 diabetes mellitus in Saudi Arabia: major challenges and possible solutions. *Current diabetes reviews* 2017;13(1):59-64.
35. Alharbi NS, Almutari R, Jones S, et al. Trends in the prevalence of type 2 diabetes mellitus and obesity in the Arabian Gulf States: Systematic review and meta-analysis. *Diabetes Research and Clinical Practice* 2014;106(2):e30-e33. doi: 10.1016/j.diabres.2014.08.019
36. Alotaibi A, Perry L, Gholizadeh L, et al. Incidence and prevalence rates of diabetes mellitus in Saudi Arabia: An overview. *Journal of Epidemiology and Global Health* 2017;7(4) doi: 10.1016/j.jegh.2017.10.001
37. Deshmukh CD, Jain A, Nahata B. Diabetes mellitus: a review. *Int J Pure App Biosci* 2015;3(3):224-30.
38. WHO. Diabetes: World Health Organization 2022 [Available from: https://www.who.int/news-room/fact-sheets/detail/diabetes accessed 4 April 2021 2021.
39. Mahler RJ, Adler ML. Type 2 Diabetes Mellitus: Update on Diagnosis, Pathophysiology, and Treatment. *The Journal of Clinical Endocrinology & Metabolism* 1999;84(4):1165-71. doi: https://doi.org/10.1210/jcem.84.4.5612
40. Al-Rubeaan K, Al-Manaa HA, Khoja TA, et al. Epidemiology of abnormal glucose metabolism in a country facing its epidemic: SAUDI-DM study. *Journal of Diabetes* 2015;7(5):622-32. doi: 10.1111/1753-0407.12224
41. Alanazi FK, Alotaibi JS, Paliadelis P, et al. Knowledge and awareness of diabetes mellitus and its risk factors in saudi arabia: Saudi Arabian Armed Forces Hospital, 2018:981-89.
42. Aljohani KA. School of Nursing and Midwifery Factors Affecting the Self-Management Practices of People with Type 2 Diabetes in Almadinah, Saudi Arabia, 2011.

43. Almahmeed W, Samir Arnaout M, Chettaoui R, et al. Coronary artery disease in Africa and the Middle East, 2012:65-72.
44. Moradi-Lakeh M, El Bcheraoui C, Tuffaha M, et al. The health of Saudi youths: Current challenges and future opportunities. *BMC Family Practice* 2016;17(1):26-26. doi: 10.1186/s12875-016-0425-z
45. Galicia-Garcia U, Benito-Vicente A, Jebari S, et al. Pathophysiology of type 2 diabetes mellitus. *International journal of molecular sciences* 2020;21(17):6275.
46. Cardel MI, Ross KM, Butryn M, et al. Acceptance-based therapy: the potential to augment behavioral interventions in the treatment of type 2 diabetes. *Nutrition & Diabetes* 2020;10(1):3-3. doi: 10.1038/s41387-020-0106-9
47. NIDDK. Symptoms & Causes of Diabetes National Institute of Diabetes and Digestive and Kidney Diseases [Available from: https://www.niddk.nih.gov/health-information/diabetes/overview/symptoms-causes accessed 4 Feb 2021 2021.
48. Daousi C, Casson IF, Gill GV, et al. Prevalence of obesity in type 2 diabetes in secondary care: Association with cardiovascular risk factors. *Postgraduate Medical Journal* 2006;82(966):280-84. doi: 10.1136/pmj.2005.039032
49. A I Al-Othaimeen 1 A K Osman MA-N. Obesity: an emerging problem in Saudi Arabia. Analysis of data from the National Nutrition Survey. *pubmed* 2007
50. Al-Zalabani AH, Al-Hamdan NA, Saeed AA. The prevalence of physical activity and its socioeconomic correlates in Kingdom of Saudi Arabia: A cross-sectional population-based national survey. *Journal of Taibah University Medical Sciences* 2015;10(2):208-15. doi: 10.1016/j.jtumed.2014.11.001
51. Physical inactivity a leading cause of disease and disability, warns WHO.
52. Ding D, Lawson KD, Kolbe-Alexander TL, et al. The economic burden of physical inactivity: a global analysis of major non-communicable diseases. *The Lancet* 2016;388(10051):1311-24. doi: 10.1016/S0140-6736(16)30383-X
53. Midhet FM, Al-Mohaimeed AA, Sharaf FK. Lifestyle related risk factors of type 2 diabetes mellitus in Saudi Arabia. *Saudi Medical Journal* 2010;31(7):768-74.
54. Moradi-Lakeh M, El Bcheraoui C, Afshin A, et al. Diet in Saudi Arabia: findings from a nationally representative survey. *Public health nutrition* 2017;20(6):1075-81.
55. Carral F, Olveira G, Salas J, et al. Care resource utilization and direct costs incurred by people with diabetes in a Spanish hospital. *Diabetes research and clinical practice* 2002;56(1):27-34. doi: 10.1016/s0168-8227(01)00342-4
56. Hex N, Bartlett C, Wright D, et al. Article: Health Economics Estimating the current and future costs of Type 1 and Type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs. doi: 10.1111/j.1464-5491.2012.03698.x
57. MoH. The Ministry Budget: Ministry of Health; 2015 [Available from: https://www.moh.gov.sa/en/Ministry/About/Pages/Budget.aspx accessed 20 June 2020 2020.
58. Reddy PH. Can Diabetes Be Controlled by Lifestyle Activities? *Current research in diabetes & obesity journal* 2017;1(4)
59. Alhowaish A. Economic costs of diabetes in Saudi Arabia. *Journal of Family and Community Medicine* 2013;20(1):1-1. doi: 10.4103/2230-8229.108174
60. Robert A, Al Dawish M, Braham R, et al. Type 2 Diabetes Mellitus in Saudi Arabia: Major Challenges and Possible Solutions. *Current Diabetes Reviews* 2016;13(1):59-64. doi: 10.2174/1573399812666160126142605
61. Naeem Z. Burden of Diabetes Mellitus in Saudi Arabia. *International Journal of Health Sciences* 2015;9(3):V-VI. doi: 10.12816/0024690
62. Alshayban D, Joseph R. Health-related quality of life among patients with type 2 diabetes mellitus in Eastern Province, Saudi Arabia: A cross-sectional study. *PLOS ONE* 2020;15(1):e0227573-e73. doi: 10.1371/journal.pone.0227573
63. Takenaka H, Sato J, Suzuki T, et al. Family issues and family functioning of Japanese outpatients with type 2 diabetes: A cross-sectional study. *BioPsychoSocial Medicine* 2013;7(1):13-13. doi: 10.1186/1751-0759-7-13

64. Senitan M, Alhaiti AH, Gillespie J, et al. The referral system between primary and secondary health care in Saudi Arabia for patients with type 2 diabetes: A systematic review: Hindawi Limited, 2017.
65. Alabdulbaqi D. A Cultural Adaptation of a Diabetes Self-Management Programme for Patients with Type 2 Diabetes Attending a Primary Health Care Centre in Saudi Arabia, 2019.
66. Al-Rubeaan KA, Youssef AM, Subhani SN, et al. A web-Based interactive diabetes registry for health care management and planning in saudi arabia. *Journal of Medical Internet Research* 2013;15(9) doi: 10.2196/jmir.2722
67. Hayes E, McCahon C, Panahi MR, et al. Alliance not compliance: Coaching strategies to improve type 2 diabetes outcomes. *Journal of the American Academy of Nurse Practitioners* 2008;20(3):155-62. doi: 10.1111/j.1745-7599.2007.00297.x
68. Wolever RQ, Jordan M, Lawson K, et al. Advancing a new evidence-based professional in health care: Job task analysis for health and wellness coaches. *BMC Health Services Research* 2016;16(1) doi: 10.1186/s12913-016-1465-8
69. Al Slamah T, Nicholl BI, Alslail FY, et al. Self-management of type 2 diabetes in gulf cooperation council countries: A systematic review. *PLOS ONE* 2017;12(12):e0189160-e60. doi: 10.1371/journal.pone.0189160
70. Pearson ML, Mattke S, Shaw R, et al. Final Contract Report Patient Self-Management Support Programs: An Evaluation, 2007.
71. Arloski M, Duluth M. Wellness Coaching for Lasting Lifestyle Change 2nd Edition2014.
72. Turner MG, John. Encyclopedia of Behavioral Medicine: Springer New York 2013.
73. Lund SH, Aspelund T, Kirby P, et al. Individualised risk assessment for diabetic retinopathy and optimisation of screening intervals: A scientific approach to reducing healthcare costs. *British Journal of Ophthalmology* 2016;100(5):683-87. doi: 10.1136/bjophthalmol-2015-307341
74. Powell CK, Hill EG, Clancy DE. The Relationship Between Health Literacy and Diabetes Knowledge and Readiness to Take Health Actions. *The Diabetes Educator* 2007;33(1) doi: 10.1177/0145721706297452
75. Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. 2002
76. Lindstrom J. Sustained reduction in the incidence of type 2 diabetes by lifestyle intervention: follow-up of the Finnish Diabetes Prevention Study. *Lancet* 2006;368:1673-79.
77. NIDDK. Diabetes Prevention Program 2022 [Available from: https://www.niddk.nih.gov/about-niddk/research-areas/diabetes/diabetes-prevention-program-dpp accessed 3 Aprile 2021 2021.
78. MoH. Chronic Disease - Diabetes Ministry Of Health2020 [Available from: https://www.moh.gov.sa/en/awarenessplateform/ChronicDisease/Pages/Diabetes.aspx accessed 9 June 2021 2021.
79. Kelly MP, Barker M. Why is changing health-related behaviour so difficult? *Public Health* 2016;136:109-16. doi: 10.1016/j.puhe.2016.03.030
80. Al Slamah T, Nicholl BI, Alslail FY, et al. Cultural adaptation of self-management of type 2 diabetes in Saudi Arabia (qualitative study). *PLOS ONE* 2020;15(7):e0232904-e04. doi: 10.1371/journal.pone.0232904
81. Gore D, Kothari A. Social determinants of health in Canada: Are healthy living initiatives there yet? A policy analysis: BioMed Central, 2012:1-14.
82. Ojo SO, Bailey DP, Brierley ML, et al. Breaking barriers: Using the behavior change wheel to develop a tailored intervention to overcome workplace inhibitors to breaking up sitting time. *BMC Public Health* 2019;19(1):1-17. doi: 10.1186/s12889-019-7468-8
83. Michie S, van Stralen MM, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implementation Science* 2011;6(1) doi: 10.1186/1748-5908-6-42
84. Atkins L, Francis J, Islam R, et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. *Implementation Science* 2017;12(1):1-18. doi: 10.1186/s13012-017-0605-9

85. Alharbi NS. TOWARDS THE HOLISTIC MANAGEMENT OF DIABETES IN SAUDI ARABIA: A MULTI-METHOD STUDY. 2018
86. AlQuaiz AM, Tayel SA. Barriers to a healthy lifestyle among patients attending primary care clinics at a university hospital in Riyadh. *Annals of Saudi Medicine* 2009;29(1):30-35. doi: 10.4103/0256-4947.51818
87. Alneami YM, Coleman CL. Risk Factors for and Barriers to Control Type-2 Diabetes among Saudi Population. *Global Journal of Health Science* 2016;8(9) doi: 10.5539/gjhs.v8n9p10
88. Michie S, Johnston M. Theories and techniques of behaviour change: Developing a cumulative science of behaviour change: Taylor & Francis Group, 2012:1-6.
89. Alzahrani AM, Albakri SBB, Alqutub TT, et al. Physical activity level and its barriers among patients with type 2 diabetes mellitus attending primary healthcare centers in Saudi Arabia. *Journal of Family Medicine and Primary Care* 2019;8(8):2671-75. doi: 10.4103/jfmpc.jfmpc_433_19
90. Bodenheimer T, Francisco Gen S. CLINICAL CROSSROADS A 63-Year-Old Man With Multiple Cardiovascular Risk Factors and Poor Adherence to Treatment Plans, 2007:2048-56.
91. Larson NI, Story MT, Nelson MC. Neighborhood Environments. Disparities in Access to Healthy Foods in the U.S: Elsevier Inc., 2009.
92. Al-Khudairy L, Stranges S, Al-Dagheri N, et al. PP09 Cultural barriers to healthy eating in Saudi adults with and without type 2 diabetes (T2D). *Journal of Epidemiology and Community Health* 2014;68(Suppl 1):A50.2-A51. doi: 10.1136/jech-2014-204726.106
93. Al-Aboudi IS, Hassali MA, Shafie AA. Knowledge, attitudes, and quality of life of type 2 diabetes patients in Riyadh, Saudi Arabia. *Journal of Pharmacy and Bioallied Sciences* 2016;8(3):195-202. doi: 10.4103/0975-7406.171683
94. Al T, Id S, Nicholl BI, et al. Cultural adaptation of self-management of type 2 diabetes in Saudi Arabia (qualitative study). 2020 doi: 10.1371/journal.pone.0232904
95. Kamel FO, Magadmi RM, Hagras MM, et al. Knowledge, attitude, and beliefs toward traditional herbal medicine use among diabetics in Jeddah Saudi Arabia. *Complementary Therapies in Clinical Practice* 2017;29:207-12. doi: 10.1016/j.ctcp.2017.10.007
96. Abahussain NA, El-Zubier AG. Diabetes knowledge among self reported diabetic female teachers: Al-khobar, saudi arabia. *Journal of family & community medicine* 2005;12(1):43-48.
97. Al-Saeedi M, Elzubier AG, Bahnassi AA, et al. Patterns of belief and use of traditional remedies by diabetic patients in Mecca, Saudi Arabia. *Eastern Mediterranean Health Journal* 2003;9(1-2):99-107.
98. Al-Saggaf Y, Williamson K. Online communities in Saudi Arabia: Evaluating the impact on culture through online semi-structured interviews. *Forum Qualitative Sozialforschung* 2004;5(3) doi: 10.17169/fqs-5.3.564
99. Dyson PA, Twenefour D, Breen C, et al. Diabetes UK evidence-based nutrition guidelines for the prevention and management of diabetes. *Diabetic Medicine* 2018;35(5):541-47. doi: 10.1111/dme.13603
100. Moore AP, Rivas CA, Stanton-Fay S, et al. Designing the Healthy Eating and Active Lifestyles for Diabetes (HEAL-D) self-management and support programme for UK African and Caribbean communities: A culturally tailored, complex intervention under-pinned by behaviour change theory. *BMC Public Health* 2019;19(1):1146-46. doi: 10.1186/s12889-019-7411-z
101. Michie S, Atkins L, West R. The behaviour change wheel. *A guide to designing interventions 1st ed Great Britain: Silverback Publishing* 2014:1003-10.
102. Federation IC. ICF Core Competencies: ICF Core Competencies, 2022.
103. Perry Z, Suzanne S. The Complete Guide to Coaching at Work2000.
104. Orji R, Vassileva J, Mandryk R. Towards an Effective Health Interventions Design: An Extension of the Health Belief Model. *Online Journal of Public Health Informatics* 2012;4(3) doi: 10.5210/ojphi.v4i3.4321
105. Jones CL, Jensen JD, Scherr CL, et al. The Health Belief Model as an Explanatory Framework in Communication Research: Exploring Parallel, Serial, and Moderated Mediation. *Health Communication* 2015;30(6):566-76. doi: 10.1080/10410236.2013.873363

106. Painter JE, Borba CPC, Hynes M, et al. The use of theory in health behavior research from 2000 to 2005: A systematic review, 2008:358-62.
107. Prochaska JO, Velicer WF. The Transtheoretical Model of Health Behavior Change. *American Journal of Health Promotion* 1997;12(1):38-48. doi: 10.4278/0890-1171-12.1.38
108. Miller WR, Zweben A, DiClemente C, et al. Motivational Enhancement Therapy manual: a clinical research guide for therapists treating individuals with alcohol abuse and dependence, 1992.
109. Deci EL, Ryan RM. The "What" and "Why" of Goal Pursuits: Human Needs and the Self-Determination of Behavior, 2000.
110. Denneson LM, Ono SS, Trevino AY, et al. The applicability of self-determination theory to health coaching: a qualitative analysis of patient experiences. *Coaching* 2019 doi: 10.1080/17521882.2019.1673457
111. Rollnick S, Miller WR. What is Motivational Interviewing? *Behavioural and Cognitive Psychotherapy* 1995;23(4):325-34. doi: 10.1017/S135246580001643X
112. Moor M, Tschannen B. Coaching psychology manual: Wellcoaches 2010.
113. William RM, Stephen R. Motivational Interviewing Helping People Change - Applications of Motivational Interviewing2009.
114. Vansteenkiste M, Sheldon KM. There's nothing more practical than a good theory: Integrating motivational interviewing and self-determination theory. *British Journal of Clinical Psychology* 2006;45(1) doi: 10.1348/014466505X34192
115. Ellis A. Reason and Emotion in Psychotherapy: New York: Stuart 1975.
116. Temmingh H, Claassen A, Van Zyl S, et al. The evaluation of a telephonic wellness coaching intervention for weight reduction and wellness improvement in a community-based cohort of persons with serious mental illness. *Journal of Nervous and Mental Disease* 2013;201(11):977-86. doi: 10.1097/NMD.0000000000000036
117. Butterworth SW, Linden A, McClay W. Health coaching as an intervention in health management programs: Adis International Ltd, 2007:299-307.
118. Peter Grinspoon MD. Health coaching is effective. Should you try it?, 2020.
119. Huffman FG, Zarini GG, Cooper V. Dietary glycemic index and load in relation to cardiovascular disease risk factors in Cuban American population. *International Journal of Food Sciences and Nutrition* 2010;61(7) doi: 10.3109/09637481003752267
120. Lindner H, Menzies D, Kelly J, et al. Coaching for Behaviour Change in Chronic Disease: A Review of the Literature and the Implications for Coaching as a Self-management Intervention, 2003.
121. Wolever RQ, Dreusicke M, Fikkan J, et al. Integrative Health Coaching for Patients With Type 2 Diabetes. *The Diabetes Educator* 2010;36(4) doi: 10.1177/0145721710371523
122. Wong-Rieger D, Rieger FP. Health coaching in diabetes: empowering patients to self-manage: Elsevier, 2013:41-44.
123. Gallé F, Di Onofrio V, Cirella A, et al. Improving Self-Management of Type 2 Diabetes in Overweight and Inactive Patients Through an Educational and Motivational Intervention Addressing Diet and Physical Activity: A Prospective Study in Naples, South Italy. *Diabetes Therapy* 2017;8(4) doi: 10.1007/s13300-017-0283-2
124. Campbell M. Framework for design and evaluation of complex interventions to improve health. *BMJ* 2000;321(7262) doi: 10.1136/bmj.321.7262.694
125. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: The new Medical Research Council guidance: British Medical Journal Publishing Group, 2008:979-83.
126. Bandura A, Bandura A. Health promotion from the perspective of social cognitive theory. *PSYCHOLOGY AND HEALTH* 1998:623--49.
127. Olsen JM, Nesbitt BJ. Health Coaching to Improve Healthy Lifestyle Behaviors: An Integrative Review. *American Journal of Health Promotion* 2010;25(1):e1-e12. doi: 10.4278/ajhp.090313-LIT-101
128. Alamri F, Radwan N, Elolemy A, et al. Effectiveness of health coaching on diabetic patients: A Systematic Review and Meta-analysis. *Traditional Medicine Research* 2019;4(314–325) doi: 10.12032/TMR20191024143

129. Almulhim AN, Goyder E, Caton SJ. Assessing the Feasibility and Acceptability of Health Coaching as a New Diabetes Management Approach for the People with Type 2 Diabetes in Saudi Arabia: A Protocol for a Mixed Methods Feasibility Study. *International Journal of Environmental Research and Public Health* 2022;19(22):15089.
130. Michie S, Richardson, M., Johnston, M., Abraham, C., Francis, J., Hardeman, W., Eccles, M.P., Cane, J., Wood, C.E. The Behavior Change Technique Taxonomy (v1) of 93 Hierarchically Clustered Techniques: Building an International Consensus for the Reporting of Behavior Change Interventions. . *Change Interventions oral Medicine* 2013;46, 81–95 doi: 10.1007/s12160-013-9486-6
131. Booth A, Noyes J, Flemming K, et al. Formulating questions to explore complex interventions within qualitative evidence synthesis. *BMJ Global Health* 2019;4(Suppl 1):e001107-e07. doi: 10.1136/bmjgh-2018-001107
132. Marsiglia FF, Booth JM. Cultural Adaptation of Interventions in Real Practice Settings. *Research on Social Work Practice* 2015;25(4) doi: 10.1177/1049731514535989
133. Bowen DJ, Kreuter M, Spring B, et al. How We Design Feasibility Studies: Am J Prev Med, 2009:452-57.
134. Orsmond GI, Cohn ES. The distinctive features of a feasibility study: Objectives and guiding questions. *OTJR Occupation, Participation and Health* 2015;35(3):169-77. doi: 10.1177/1539449215578649
135. O'Cathain A, Croot L, Duncan E, et al. Guidance on how to develop complex interventions to improve health and healthcare. *BMJ Open* 2019;9(8) doi: 10.1136/bmjopen-2019-029954
136. Craig P, Ruggiero ED, Frohlich KL, et al. Taking account of context in the population health intervention research process. 2018
137. Saunders M, Lewis P, Thornhill A. Research methods for business students: Pearson education 2009.
138. Saunders M, Tosey P. The layers of research design. *Rapport* 2013(Winter):58-59.
139. Crotty MJ. The foundations of social research: Meaning and perspective in the research process. *The foundations of social research* 1998:1-256.
140. Creswell JW, Clark VLP. Designing and conducting mixed methods research: Sage publications 2017.
141. Cresswell JW, Plano Clark VL. Designing and conducting mixed methods research. 2011
142. Fetters MD, Curry LA, Creswell JW. Achieving integration in mixed methods designs—principles and practices. *Health services research* 2013;48(6pt2):2134-56.
143. Guba EG, Lincoln YS. Competing paradigms in qualitative research. *Handbook of qualitative research* 1994;2(163-194):105.
144. Anney VN. Ensuring the quality of the findings of qualitative research: Looking at trustworthiness criteria. *Journal of emerging trends in educational research and policy studies* 2014;5(2):272-81.
145. Polit DF, & Beck, C.T. . Essentials of nursing research: Appraising evidence for nursing practice. 8th ed ed. Philadelphia, PA: Wolters Kluwer/Lippincott Williams & Wilkins 2014.
146. Shenton AK. Strategies for ensuring trustworthiness in qualitative research projects. *Education for information* 2004;22(2):63-75.
147. Eldridge SM, Chan CL, Campbell MJ, et al. CONSORT 2010 statement: Extension to randomised pilot and feasibility trials. *The BMJ* 2016;355 doi: 10.1136/bmj.i5239
148. Michie S, Prestwich A. Are interventions theory-based? Development of a theory coding scheme. *Health psychology : official journal of the Division of Health Psychology, American Psychological Association* 2010;29(1):1-8. doi: 10.1037/a0016939
149. Almulhim AN, Hartley H, Norman P, et al. Behavioural Change Techniques in Health Coaching-Based Interventions for Type 2 Diabetes: A Systematic Review and Meta-Analysis. *BMC Public Health* 2023;23(1):1-21.
150. Prochaska J, Velicer W. Behavior Change The Transtheoretical Model of Health Behavior Change. 2002
151. Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ (Online)* 2015;350 doi: 10.1136/bmj.h1258
152. Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: Results from 7 studies and a revised scale. *Diabetes Care* 2000;23(7):943-50. doi: 10.2337/diacare.23.7.943

153. Eigenmann C, Colagiuri R, Skinner T, et al. Are current psychometric tools suitable for measuring outcomes of diabetes education? *Diabetic Medicine* 2009;26(4):425-36.
154. Schmitt A, Reimer A, Hermanns N, et al. Assessing diabetes self-management with the diabetes self-management questionnaire (DSMQ) can help analyse behavioural problems related to reduced glycaemic control. *PloS one* 2016;11(3):e0150774.
155. Consanu G, Erdogan S. Influence of psychosocial factors on self-care behaviors andglycemic control in Turkish patients with type 2 diabetes mellistus. *Journal ofTranscultural Nursing* 2013
156. Choi EJ, Nam M, Kim SH, et al. Psychometric properties of a Korean version of the summary of diabetes self-care activities measure. *International Journal of Nursing Studies* 2011;48(3):333-37.
157. Bean D, Cundy T, Petrie KJ. Ethnic differences in illness perceptions, self-efficacy and diabetes self-care. *Psychology and Health* 2007;22(7):787-811.
158. AlJohani KA, Kendall GE, Snider PD. Psychometric evaluation of the summary of diabetes self-care activities–Arabic (SDSCA-Arabic) translation and analysis process. *Journal of Transcultural Nursing* 2016;27(1):65-72.
159. Alsomali SI. An investigation of self-care practice and social support of patients with type 2 diabetes in Saudi Arabia: University of Salford (United Kingdom) 2019.
160. Al-Rawashdeh I. Self-care behaviours and related psychosocial factors in men and women with Type 2 Diabetes Mellitus in Jordan: a cross sectional study, 2017.
161. Sukkarieh-Haraty O, Howard E. Psychometric Properties of the Arabic Version of the Summary of Diabetes Self-Care Activities Instrument. *Research & Theory for Nursing Practice* 2016;30(1)
162. Stanford Patient Education Research C. Stanford Self-Efficacy for Diabetes Scale, 2009.
163. Lorig K, Ritter PL, Villa FJ, et al. Community-based peer-led diabetes self-management. *The diabetes educator* 2009;35(4):641-51.
164. Kerari A. The psychometric properties of the Diabetes Self-Efficacy Scale in Saudis with type 2 diabetes. *Nursing Open* 2023
165. Dejesus RS, Clark MM, Finney Rutten LJ, et al. Wellness Coaching to Improve Lifestyle Behaviors Among Adults With Prediabetes: Patients' Experience and Perceptions to Participation. *pubmed* 2018 doi: 10.1177/2374373518769118
166. Who. Process of translation and adaptation of instruments, 2013.
167. Leydens JA, Moskal BM, Pavelich MJ. Qualitative methods used in the assessment of engineering education. *Journal of engineering education* 2004;93(1):65-72.
168. Gill P, Baillie J. Interviews and focus groups in qualitative research: An update for the digital age. *British dental journal* 2018;225(7):668-72.
169. Phillippi J, Lauderdale J. A guide to field notes for qualitative research: Context and conversation. *Qualitative health research* 2018;28(3):381-88.
170. Debus M. Methodological review: a handbook for excellence in focus group research: Academy for Educational Development 1988.
171. Rabiee F. Focus-group interview and data analysis. *Proceedings of the Nutrition Society* 2004;63(4):655-60. doi: 10.1079/pns2004399
172. O'Cathain A, Hoddinott P, Lewin S, et al. Maximising the impact of qualitative research in feasibility studies for randomised controlled trials: guidance for researchers. *Pilot and feasibility studies* 2015;1(1):1-13.
173. Gray D. Doing research in the real world. 2nd ed. ed: SAGE 2009.
174. Ethnography : principles in practice / Martyn Hammersley and Paul Atkinson. - Trove.
175. Braun V, Clarke V. Using thematic analysis in psychology. *Qualitative Research in Psychology* 2006;3(2):77-101. doi: 10.1191/1478088706qp063oa
176. O'Cathain A, Murphy E, Nicholl J. Three techniques for integrating data in mixed methods studies. *Bmj* 2010;341
177. McCrudden MT, Marchand G, Schutz PA. Joint displays for mixed methods research in psychology. *Methods in Psychology* 2021;5:100067.
178. Morgan DL. Commentary—After triangulation, what next?: Sage Publications Sage CA: Los Angeles, CA, 2019:6-11.

179. Julious S. Sample Size Methods used in the SampSize App. Pharmaceutical Statistics: White Rose Repository, 2023.
180. Lin CL, Huang LC, Chang YT, et al. Effectiveness of health coaching in diabetes control and lifestyle improvement: A randomized-controlled trial. *Nutrients* 2021;13(11) doi: 10.3390/NU13113878
181. Whitehead AL, Julious SA, Cooper CL, et al. Estimating the sample size for a pilot randomised trial to minimise the overall trial sample size for the external pilot and main trial for a continuous outcome variable. *Statistical methods in medical research* 2016;25(3):1057-73.
182. Sherifali D, Brozic A, Agema P, et al. Effect of Diabetes Health Coaching on Glycemic Control and Quality of Life in Adults Living With Type 2 Diabetes: A Community-Based, Randomized, Controlled Trial. *Canadian journal of diabetes* 2021;45(7):594-600. doi: 10.1016/J.JCJD.2020.11.012
183. Lameijer A, Fokkert M, Edens M, et al. Determinants of HbA1c reduction with FreeStyle Libre flash glucose monitoring (FLARE-NL 5). *Journal of clinical & translational endocrinology* 2020;22:100237.
184. DeMers D, Wachs D. Physiology, Mean Arterial Pressure (2021). *Disponıvel em http://www ncbi nlm nih gov/pubmed/30855814 Ultimo acesso* 2020;14(03)
185. Basak Cinar A, Schou L. Health promotion for patients with diabetes: health coaching or formal health education? *International Dental Journal* 2014;64(1) doi: 10.1111/idj.12058
186. Kim MT, Kim KB, Huh B, et al. The Effect of a Community-Based Self-Help Intervention. *American Journal of Preventive Medicine* 2015;49(5) doi: 10.1016/j.amepre.2015.04.033
187. Cho J-H, Kwon H-S, Kim H-S, et al. Effects on diabetes management of a health-care provider mediated, remote coaching system via a PDA-type glucometer and the Internet. *Journal of Telemedicine and Telecare* 2011;17(7) doi: 10.1258/jtt.2011.100913
188. Eysenbach G, Group C-E. CONSORT-EHEALTH: improving and standardizing evaluation reports of Web-based and mobile health interventions. *Journal of medical Internet research* 2011;13(4):e1923.
189. Lee EC, Whitehead AL, Jacques RM, et al. The statistical interpretation of pilot trials: should significance thresholds be reconsidered? *BMC medical research methodology* 2014;14(1):1-8.
190. Diagnosis | ADA.
191. Ruggiero L, Moadsiri A, Butler P, et al. Supporting Diabetes Self-Care in Underserved Populations. *The Diabetes Educator* 2010;36(1) doi: 10.1177/0145721709355487
192. Whittemore R, Melkus GDE, Sullivan A, et al. A Nurse-Coaching Intervention for Women With Type 2 Diabetes. *The Diabetes Educator* 2004;30(5) doi: 10.1177/014572170403000515
193. Sacco WP, Malone JI, Morrison AD, et al. Effect of a brief, regular telephone intervention by paraprofessionals for type 2 diabetes. *Journal of Behavioral Medicine* 2009;32(4) doi: 10.1007/s10865-009-9209-4
194. Wolever RQ, Dreusicke MH. Integrative health coaching: A behavior skills approach that improves hba1c and pharmacy claims-derived medication adherence. *BMJ Open Diabetes Research and Care* 2016;4(1) doi: 10.1136/bmjdrc-2016-000201
195. Chronic Disease - Diabetes.
196. Chronic Disease - Diabetes.
197. Mbuagbaw L, Kosa SD, Lawson DO, et al. The reporting of progression criteria in protocols of pilot trials designed to assess the feasibility of main trials is insufficient: a meta-epidemiological study. *Pilot and Feasibility Studies* 2019;5(1):1-8.
198. Frosch DL. Evaluation of a Behavior Support Intervention for Patients With Poorly Controlled Diabetes. *Archives of Internal Medicine* 2011;171(22) doi: 10.1001/archinternmed.2011.497
199. Doyle L, Brady A-M, Byrne G. An overview of mixed methods research. *Journal of research in nursing* 2009;14(2):175-85.
200. Holloway I, Galvin K. Qualitative research in nursing and healthcare: John Wiley & Sons 2016.
201. Organization WH. WHO Director-General's opening remarks at the media briefing on COVID-19-11 March 2020: Geneva, Switzerland, 2020.
202. Clarke V, Braun V. Thematic analysis: a practical guide. *Thematic Analysis* 2021:1-100.

203. Thorogood N, Green J. Qualitative methods for health research. *Qualitative methods for health research* 2018:1-440.

Appendices

Appendix 1: The APEASE criteria

Acceptability	How far is it acceptable to key stakeholders? This includes the target group, potential funders, practitioners delivering the interventions and relevant community and commercial groups.
Practicability	Can it be implemented at scale in the intended context, with available material and human resources? What would need to be done to ensure that the resources and personnel were in place, and is the intervention sustainable?
Effectiveness	How effective is it (likely to be) in achieving the policy objective(s)? How far will it reach the intended target group and how large an effect will it have on those who are reached?
Affordability	How far can it be afforded when delivered at the scale intended? Can the necessary budget be found for it? Will it provide a good return on investment?
Spill-over effects (Side-effects)	What extraneous adverse (or beneficial) outcomes might it lead to? How important are they and what is the likelihood that they will occur?
Equity	How far will it, or is it likely to, increase or decrease differences between advantaged and disadvantaged sectors of society?

(Source: Michie et al. The behaviour change wheel, 2014) [101]

Appendix 2: Summary of Diabetes Self Care Activity (SDSCA)

Summary of Diabetes Self Care activity[152]

SDSCA

The questions below ask about your diabetes self-care activities during the past seven days. If you were sick during the past seven days please think back to the last seven days when you were not sick.

Diet	**Number of days**							
1. On average, over the past month, how many days per week have you followed your eating plan?	0	1	2	3	4	5	6	7
2. On how many of the last seven days did you eat five or more servings of fruits and vegetables?	0	1	2	3	4	5	6	7
3. On how many of the last seven days did you eat high fat foods such as red meat or full-fat dairy products?	0	1	2	3	4	5	6	7
4. On how many of the last seven days did you space carbohydrates evenly through the day?	0	1	2	3	4	5	6	7
5. On how many of the last seven days have you followed a healthful eating plan?	0	1	2	3	4	5	6	7

Exercise	**Number of Days**							
1.. On how many of the last seven days did you participate in at least 30 minutes of physical activity?	0	1	2	3	4	5	6	7
2. On how many of the last seven days did you participate in a specific exercise session (such as such swimming, walking, biking) other than what you do around the house or as part of your work?	0	1	2	3	4	5	6	7

Permission to use the Summary of Diabetes Self Care Activity (SDSCA) Scale

new message(s) regarding your request.

ceive your answer(s), please login to ePROVIDE platform and access the details of your request to reply.

	From	Message
	Marie-Sidonie Edieux	Dear Abdullah, Thank you for your interest in the SDSCA - Summary of Diabetes Self-Care Activities. As a not-funded academic user, you will not be charged for the use of this questionnaire (https://eprovide.mapi-trust.org/instruments/summary-of-diabetes-self-care-activities#need_this_questionnaire). You can use Online Distribution to download any available translations of the questionnaire from ePROVIDE. Please refer to the Instructions to download a questionnaire for assistance with this process.

Appendix 3: Self-efficacy Scale for Diabetes

SMRC
Self-Management Resource Center

Self-Efficacy for Diabetes

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time.

1. How confident do you feel that you can eat your meals every 4 to 5 hours every day, including breakfast every day?
2. How confident do you feel that you can follow your diet when you have to prepare or share food with other people who do not have diabetes?
3. How confident do you feel that you can choose the appropriate foods to eat when you are hungry (for example, snacks)?
4. How confident do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week?
5. How confident do you feel that you can do something to prevent your blood sugar level from dropping when you exercise?
6. How confident do you feel that you know what to do when your blood sugar level goes higher or lower than it should be?
7. How confident do you feel that you can judge when the changes in your illness mean you should visit the doctor?
8. How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do?

not at all confident 1 2 3 4 5 6 7 8 9 10 totally confident

Scoring

The score for each item is the number circled. If two consecutive numbers are circled, code the lower number (less self-efficacy). If the numbers are not consecutive, do not score the item. The score for the scale is the mean of the eight items. If more than two items are missing, do not score the scale. Higher number indicates higher self-efficacy.

Characteristics

Tested on 186 subjects with diabetes.

No. of Items	Observed Range	Mean	Standard Deviation	Internal Consistency Reliability	Test-Retest Reliability
8	1-10	6.87	1.76	.828	NA

Source of Psychometric Data

Stanford English Diabetes Self-Management study. Study reported in Lorig K, Ritter PL, Villa FJ, Armas J. Community-Based Peer-Led Diabetes Self-Management: A Randomized Trial. The Diabetes Educator 2009; Jul-Aug;35(4):641-51.

Comments

This 8-item scale was originally developed and tested in Spanish for the Diabetes Self-Management study. For internet studies, we add radio buttons below each number. There is another way that we use to format these items, which takes up less space on a questionnaire, shown also in the PDF document. This scale is available in Spanish.

References

Unpublished.

This scale is free to use without permission

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Palo Alto CA 94303
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www.selfmanagementresource.com

Appendix 4 : Likert-Scale Satisfaction Questionnaire

1. To what extent did participating in wellness coaching change you/your behaviour?

Not at all		A little bit		Somewhat		Quite a bit			Very Much	
0	1	2	3	4	5	6	7	8	9	10

Please explain: _____

2. What was most helpful about participating in wellness coaching?

_____

3. What was least helpful about participating in wellness coaching?

_____

4. What about your relationship with the coach was helpful to you if anything?

Please explain: _____

5. To what extent did participating in wellness coaching help you create a personal vision of wellness (how you want to see yourself in the future with regard to wellness)?

Not at all		A little bit		Somewhat		Quite a bit			Very Much	
0	1	2	3	4	5	6	7	8	9	10

Please explain: _____

6. To what extent did participating in wellness coaching increase your confidence to take steps toward greater wellness?

Not at all		A little bit		Somewhat		Quite a bit			Very Much	
0	1	2	3	4	5	6	7	8	9	10

Please explain: _____

7. To what extent did participating in wellness coaching increase your motivation to take steps toward greater wellness?

Not at all		A little bit		Somewhat		Quite a bit			Very Much	
0	1	2	3	4	5	6	7	8	9	10

Please explain: _____

8. To what extent did participating in wellness coaching increase your use of goal setting skills?

Not at all		A little bit		Somewhat		Quite a bit			Very Much	
0	1	2	3	4	5	6	7	8	9	10

Please explain: _____

9. To what extent did participating in wellness coaching increase your use of problem-solving skills?

Not at all		A little bit		Somewhat		Quite a bit			Very Much	
0	1	2	3	4	5	6	7	8	9	10

Please explain: _____

10. To what extent did participating in wellness coaching help you get back on track after running into barriers/problems?

Not at all		A little bit		Somewhat		Quite a bit			Very Much	
0	1	2	3	4	5	6	7	8	9	10

Please explain: _____

11. To what extent did participating in wellness coaching help you achieve greater wellness?

Not at all		A little bit		Somewhat		Quite a bit			Very Much	
0	1	2	3	4	5	6	7	8	9	10

Please explain: _____

12. Do you think you'll continue with changes you've made based on participating in wellness coaching?

☐ Yes ☐ No

Please explain: _____

13. Did your wellness coaching experience meet your expectations?

☐ Yes ☐ No

Please explain: _____

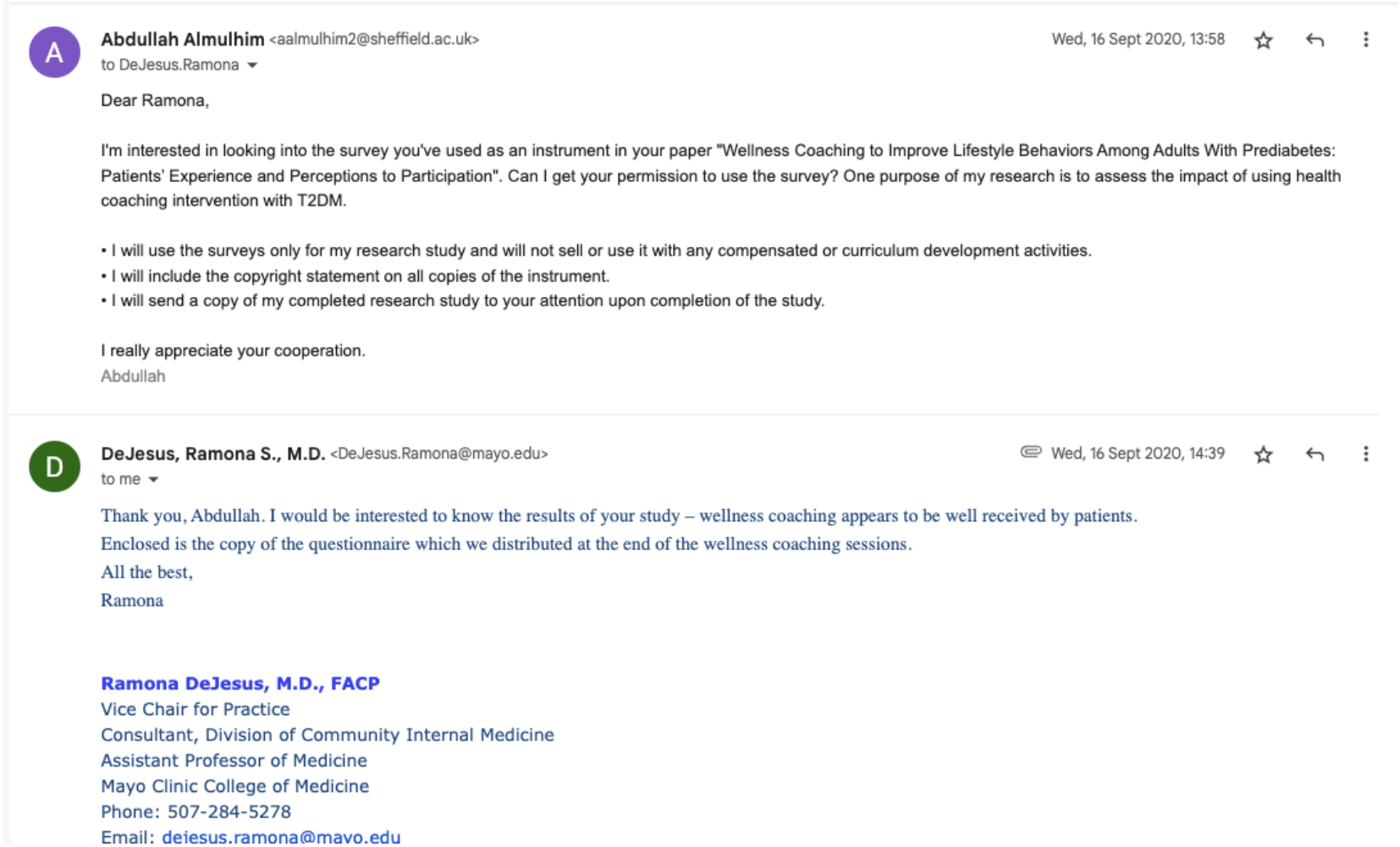
14. Would you recommend wellness coaching to others?

☐ Yes ☐ No

Please describe why or why not: _____

(Adapted from Wellness Coaching survey at Dan Abrahams Healthy Living Centre)

Appendix 5: Permission to use Likert-scale Satisfaction Questionnaire



Abdullah Almulhim <aalmulhim2@sheffield.ac.uk> Wed, 16 Sept 2020, 13:58
to DeJesus.Ramona

Dear Ramona,

I'm interested in looking into the survey you've used as an instrument in your paper "Wellness Coaching to Improve Lifestyle Behaviors Among Adults With Prediabetes: Patients' Experience and Perceptions to Participation". Can I get your permission to use the survey? One purpose of my research is to assess the impact of using health coaching intervention with T2DM.

- I will use the surveys only for my research study and will not sell or use it with any compensated or curriculum development activities.
- I will include the copyright statement on all copies of the instrument.
- I will send a copy of my completed research study to your attention upon completion of the study.

I really appreciate your cooperation.
Abdullah

DeJesus, Ramona S., M.D. <DeJesus.Ramona@mayo.edu> Wed, 16 Sept 2020, 14:39
to me

Thank you, Abdullah. I would be interested to know the results of your study – wellness coaching appears to be well received by patients.
Enclosed is the copy of the questionnaire which we distributed at the end of the wellness coaching sessions.
All the best,
Ramona

Ramona DeJesus, M.D., FACP
Vice Chair for Practice
Consultant, Division of Community Internal Medicine
Assistant Professor of Medicine
Mayo Clinic College of Medicine
Phone: 507-284-5278
Email: dejesus.ramona@mayo.edu

Appendix 6: Study questionnaire (English Version)

The study's questionnaires for data collection purposes

Your cooperation in completing this questionnaire is greatly appreciated as a part of my PhD study in Public Health at the University of Sheffield-UK. This survey is a crucial part of the study assessment to explore the feasibility of applying health coaching with type 2 diabetes people in SA. You might need a short time (about 10-15 minutes) to do the questionnaire.

Please note:

- The time of completing the questionnaire is flexible if you feel tired or wish to do it later on
- All responses and information will be strictly confidential and protected.
- Questionnaire copies will be kept with the researcher only, and no access will be given to a third party

For any information, please feel free to contact me Abdullah Almulhim on

Mobile: 0541333494

Email:aalmulhim2@sheffield.ac.uk

Part I (At the Intervention Baseline & Endpoint)

A. **Demographic information section:**
What is your age? ----------
What is your level of education? Illiterate Primary school Secondary school High School Master or PhD Other
What is your current marital status? Single Married Divorced Would rather not say
What is your monthly income? Less than 5000 5000- 10000 10000-15000 more than 150000 Would rather not say
How long have you lived with diabetes?
Do you take medication for diabetes? Yes No
How confident you are in doing certain activities? **We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time. Please circle the number that corresponds to your confidence that youcan do the tasks regularly at the present time.**
1-How confident do you feel that you can eat your meals every 4 to 5 hours every day, includingbreakfast every day? **Not confident at all 1 2 3 4 5 6 7 8 9 10 Totally confident**
2-How confident do you feel that you can follow your diet when you have to prepare or share food **with other people who do not have diabetes?** **Not confident at all 1 2 3 4 5 6 7 8 9 10 Totally confident**
3-How confident do you feel that you can choose the appropriate foods to eat when you are hungry **(For example, snacks)?** **Not confident at all 1 2 3 4 5 6 7 8 9 10 Totally confident**
4-How confident do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week? **Not confident at all 1 2 3 4 5 6 7 8 9 10 Totally confident**
5-How confident do you feel that you can do something to prevent your blood sugar level from **dropping when you exercise?** **Not confident at all 1 2 3 4 5 6 7 8 9 10 Totally confident**

6- How confident do you feel that you know what to do when your blood sugar level goes higher or lower than it should be?

Not confident at all 1 2 3 4 5 6 7 8 9 10 **Totally confident**

7- How confident do you feel that you can judge when the changes in your illness mean you should visit the doctor?

Not confident at all 1 2 3 4 5 6 7 8 9 10 **Totally confident**

8- How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do?

Not confident at all 1 2 3 4 5 6 7 8 9 10 **Totally confident**

C. Self-Care section:

The questions below ask about your diabetes self-care activities during the past seven days. If you were sick during the past seven days, please think back to the lastseven days when you were not sick.

1/ Diet

1- On average, over the past month, how many days per week have you followed your eating plan?

Number of days 0 1 2 3 4 5 6 7

2- On how many of the last seven days did you eat five or more servingsof fruits and vegetables?

Number of days 0 1 2 3 4 5 6 7

3- On how many of the last seven days did you eat high fat foods such asred meat or full-fat dairy products?

Number of days 0 1 2 3 4 5 6 7

4- On how many of the last seven days did you space carbohydratesevenly through the day?

Number of days 0 1 2 3 4 5 6 7

5- On how many of the last seven days have you followed a healthfuleating plan?

Number of days 0 1 2 3 4 5 6 7

2/ Exercise

6- On how many of the last seven days did you participate in at least 30minutes of physical activity?

Number of days 0 1 2 3 4 5 6 7

7- On how many of the last seven days did you participate in a specificexercise session (such as such swimming, walking, biking) other than what you do around the house or as part of your work?

Number of days 0 1 2 3 4 5 6 7

Part II (At the Intervention Endpoint)

D. SATISFACTION QUESTIONNAIRE

1. To what extent did participating in wellness coaching change you/your behaviour?

Not at all		A little bit		Somewhat		Quite a bit			Very Much	
0	1	2	3	4	5	6	7	8	9	10

Please explain: _____

2. What was most helpful about participating in wellness coaching?

_____

3. What was least helpful about participating in wellness coaching?

_____

4. What about your relationship with the coach was helpful to you if anything?

Please explain: _____

5. To what extent did participating in wellness coaching help you create a personal vision of wellness (how you want to see yourself in the future with regard to wellness)?

Not at all		A little bit		Somewhat		Quite a bit			Very Much	
0	1	2	3	4	5	6	7	8	9	10

Please explain: _____

6. To what extent did participating in wellness coaching increase your confidence to take steps toward greater wellness?

Not at all		A little bit		Somewhat		Quite a bit			Very Much	
0	1	2	3	4	5	6	7	8	9	10

Please explain: _____

7. To what extent did participating in wellness coaching increase your motivation to take steps toward greater wellness?

Not at all		A little bit		Somewhat		Quite a bit			Very Much	
0	1	2	3	4	5	6	7	8	9	10

Please explain: _____

8. To what extent did participating in wellness coaching increase your use of goal setting skills?

Not at all		A little bit		Somewhat		Quite a bit			Very Much	
0	1	2	3	4	5	6	7	8	9	10

Please explain: _____

9. To what extent did participating in wellness coaching increase your use of problem-solving skills?

Not at all		A little bit		Somewhat		Quite a bit			Very Much	
0	1	2	3	4	5	6	7	8	9	10

Please explain: _____

10. To what extent did participating in wellness coaching help you get back on track after running into barriers/problems?

Not at all		A little bit		Somewhat		Quite a bit			Very Much	
0	1	2	3	4	5	6	7	8	9	10

Please explain: _____

11. To what extent did participating in wellness coaching help you achieve greater wellness?

Not at all		A little bit		Somewhat		Quite a bit			Very Much	
0	1	2	3	4	5	6	7	8	9	10

Please explain: _____

12. Do you think you'll continue with changes you've made based on participating in wellness coaching?

☐ Yes ☐ No

Please explain: _____

13. Did your wellness coaching experience meet your expectations?

☐ Yes ☐ No

Please explain: _____

14. Would you recommend wellness coaching to others?

☐ Yes ☐ No

Please describe why or why not: _____

Appendix 7 : Study questionnaire (Arabic Version)

استبيان الدراسة لغرض جمع البيانات

أقدر لك تعاونك في اكمال هذا الاستبيان كجزء من بحثي في الدكتوراه في الصحة العامة في جامعة شيفيلد - المملكة المتحدة. هذا الاستبيان يشكل جزءاً هاماً لتقييم واستكشاف جدوى تطبيق التدريب الصحي مع المصابين بالسكري النوع 2 في المملكة العربية السعودية. قد تحتاج إلى وقت قصير (حوالي 15-20 دقيقة) لإكمال بالاستبيان.

يرجى الملاحظة:

-يمكنك ملء الاستبيان في الوقت المناسب لك، فإذا شعرت بالتعب أو ترغب في القيام بذلك لاحقًا فلامانع من ذلك

-جميع الردود والمعلومات ستكون سرية للغاية ومحمية.

- سيتم الاحتفاظ بنسخ الاستبيان لدى الباحث فقط ولن يتم منح وصول لطرف ثالث

لمزيد من المعلومات او الاستفسارات، لا تتردد في الاتصال بي عبد الله الملحم على

الجوال: 0966541333494

بريد إلكتروني: aalmulhim2@sheffield.ac.uk

الجزء الاول (استبيان قبل البداية وعند نهاية التدخل)

أ. المعلومات الشخصية
كم عمرك؟ ----------
ما هو المستوى التعليمي؟ أمي ابتدائي متوسط ثانوي ماجستير أو دكتوراه أخرى
ماهي الحالة الاجتماعية؟ أعزب متزوج منفصل أفضل عدم الإفصاح
ما هو دخلك الشهري؟ اقل من ٥٠٠٠ ٥٠٠٠- ١٠٠٠٠ ١٠٠٠٠- ١٥٠٠٠ أكثر من ١٥٠٠٠ أفضل عدم الإفصاح
منذ متى وانت مصاب بمرض السكري؟
هل تسير على خطه علاجيه (ادوية) للسكر؟ نعم لا
ب. ما مدى ثقتك في القيام بأنشطة معينة؟ نود أن نعرف مدى ثقتك في القيام بأنشطة معينة. لكل من الأسئلة التالية، يرجى اختيار الرقم الذي يتوافق مع ثقتك في أنه يمكنك أداء المهام بانتظام في الوقت الحالي. يرجى وضع دائرة حول الرقم الذي يتوافق مع ثقتك في أنه يمكنك أداء المهام بانتظام في الوقت الحالي.

ما مدى ثقتك في أنه يمكنك تناول وجباتك كل 4 إلى 5 ساعات كل يوم ، بما في ذلك وجبة الإفطار كل يوم؟

لست واثقًا على الإطلاق 1 2 3 4 5 6 7 8 9 10 واثق تمامًا

ما مدى ثقتك في أنه يمكنك اتباع نظامك الغذائي عندما يتعين عليك إعداد الطعام أو مشاركته مع أشخاص آخرين لا يعانون من مرض السكري؟

لست واثقًا على الإطلاق 1 2 3 4 5 6 7 8 9 10 واثق تمامًا

ما مدى ثقتك في أنه يمكنك اختيار الأطعمة المناسبة لتناولها عندما تكون جائعًا (على سبيل المثال الوجبات الخفيفة)؟

لست واثقًا على الإطلاق 1 2 3 4 5 6 7 8 9 10 واثق تمامًا

ما مدى ثقتك في انه يمكنك ممارسة الرياضة من 15 إلى 30 دقيقة، من 4 إلى 5 مرات في الاسبوع؟

لست واثقًا على الإطلاق 1 2 3 4 5 6 7 8 9 10 واثق تمامًا

ما مدى ثقتك في أنه يمكنك القيام بشيء لمنع انخفاض مستوى السكر في الدم عند ممارسة الرياضة؟

لست واثقًا على الإطلاق 1 2 3 4 5 6 7 8 9 10 واثق تمامًا

ما مدى ثقتك في أنك تعرف ما يجب أن تفعله عندما يرتفع مستوى السكر في الدم أو ينخفض عما يجب أن يكون؟

لست واثقًا على الإطلاق 1 2 3 4 5 6 7 8 9 10 واثق تمامًا

ما مدى ثقتك في أنه يمكنك الحكم واتخاذ قرار عندما تلاحظ تغييرات في مرضك أنه يتوجب عليك بزيارة الطبيب؟

لست واثقًا على الإطلاق 1 2 3 4 5 6 7 8 9 10 واثق تمامًا

ما مدى ثقتك في قدرتك على التحكم في مرض السكري بحيث لا يتعارض مع الأشياء التي تريد أن تفعلها؟

لست واثقًا على الإطلاق 1 2 3 4 5 6 7 8 9 10 واثق تمامًا

ج. الرعاية الذاتية:

الأسئلة أدناه تناقش أنشطة الرعاية الذاتية لمريض السكري خلال الأيام السبعة الماضية.

١/ التغذية

في المتوسط، خلال الشهر الماضي، كم يومًا في الأسبوع اتبعت خطة الأكل الخاصة بمرض السكري كما تم الاتفاق عليه مع المدرب الصحي ؟

عدد الأيام 0 1 2 3 4 5 6 7

كم مرة خلال الأيام السبعة الماضية تناولت خمس حصص أو أكثر من الفاكهة والخضروات؟

عدد الأيام 0 1 2 3 4 5 6 7

كم مرة خلال الأيام السبعة الماضية تناولت أطعمة غنية بالدهون مثل اللحوم الحمراء أو منتجات الألبان كاملة الدسم؟

عدد الأيام 0 1 2 3 4 5 6 7

كم مرة خلال الأيام السبعة الماضية قمت بتوزيع الكربوهيدرات بالتساوي على مدار اليوم؟

عدد الأيام 0 1 2 3 4 5 6 7

كم مرة خلال الأيام السبعة الماضية اتبعت خطة غذائية صحية خاصه بك؟

عدد الأيام 0 1 2 3 4 5 6 7

٢/ النشاط الرياضي

كم مرة خلال الأيام السبعة الماضية شاركت في 30 دقيقة على الأقل من النشاط البدني؟

عدد الأيام 0 1 2 3 4 5 6 7

كم مرة خلال الأيام السبعة الماضية شاركت في جلسة تمارين معينة (مثل السباحة والمشي وركوب الدراجات) بخلاف ما تفعله في المنزل أو كجزء من عملك؟ عدد الأيام 0 1 2 3 4 5 6 7

الجزء الثاني (استبيان عند نهاية التدخل)

د. استبيان مدى الرضى عن البرنامج

إلى أي مدى ساهمت المشاركة في التدريب الصحي في تغيير سلوك / سلوكك؟

ليس على الإطلاق		قليلا		إلى حد ما		قليلا جدا		كثيرا جدا		
0	1	2	3	4	5	6	7	8	9	10

الرجاء التوضيح أكثر:

_____

_____

ما أكثر ما كان مفيدًا في المشاركة في برنامج التدريب الصحي؟

_____

_____

ما الذي كان أقل فائدة في المشاركة في برنامج التدريب الصحي؟

_____

_____

هل كانت العلاقه مع المدرب مفيدة بالنسبة لك؟

الرجاء التوضيح أكثر:

_____

_____

إلى أي مدى ساعدتك المشاركة في برنامج التدريب الصحي على تكوين رؤية صحية واضحة (كيف تريد أن ترى نفسك في المستقبل فيما يتعلق بالصحة)؟

ليس على الإطلاق		قليلا		إلى حد ما		قليلا جدا		كثيرا جدا		
0	1	2	3	4	5	6	7	8	9	10

الرجاء التوضيح أكثر:

_____

_____

إلى أي مدى أدت المشاركة في برنامج التدريب الصحي إلى زيادة ثقتك في اتخاذ خطوات نحو مزيد من حياة أكثرصحية؟

ليس على الإطلاق		قليلا		إلى حد ما		قليلا جدا		كثيرا جدا		
0	1	2	3	4	5	6	7	8	9	10

الرجاء التوضيح أكثر:

_____

_____

إلى أي مدى أدت المشاركة في برنامج التدريب إلى زيادة حافزك لاتخاذ خطوات نحو مزيد من حياة أكثرصحية مستقبلا؟

كثيرا جدا			قليلا جدا		إلى حد ما		قليلا		ليس على الإطلاق
10	9	8	7	6	5	4	3	2	1	0

الرجاء التوضيح أكثر:

_____

_____

إلى أي مدى أدت المشاركة في برنامج التدريب الصحي إلى زيادة استخدامك لمهارات تحديد الأهداف؟

كثيرا جدا			قليلا جدا		إلى حد ما		قليلا		ليس على الإطلاق
10	9	8	7	6	5	4	3	2	1	0

الرجاء التوضيح أكثر:

_____

_____

إلى أي مدى أدت المشاركة في برنامج التدريب الصحي إلى زيادة استخدامك لمهارات حل المشكلات؟

كثيرا جدا			قليلا جدا		إلى حد ما		قليلا		ليس على الإطلاق
10	9	8	7	6	5	4	3	2	1	0

الرجاء التوضيح أكثر:

_____

_____

إلى أي مدى ساعدتك المشاركة في برنامج التدريب الصحي على العودة إلى المسار الصحيح بعد مواجهة عوائق / مشاكل؟

كثيرا جدا			قليلا جدا		إلى حد ما		قليلا		ليس على الإطلاق
10	9	8	7	6	5	4	3	2	1	0

الرجاء التوضيح أكثر:

_____

_____

إلى أي مدى ساعدتك المشاركة في برنامج التدريب الصحي على تحقيق قدر أكبر من الصحة؟

ليس على الإطلاق		قليلا		إلى حد ما		قليلا جدا		كثيرا جدا		
0	1	2	3	4	5	6	7	8	9	10

الرجاء التوضيح أكثر:

_____

_____

هل تعتقد أنك ستستمر في التغييرات التي أجريتها بناءً على المشاركة في برنامج التدريب الصحي؟

☐ نعم ☐ لا

الرجاء التوضيح أكثر:

_____

_____

هل كانت تجربتك في برنامج التدريب الصحي تلبي توقعاتك؟

☐ نعم ☐ لا

الرجاء التوضيح أكثر:

_____

_____

هل تنصح الآخرين بالمشاركة في برامج التدريب الصحي؟

☐ نعم ☐ لا

الرجاء ذكر السبب سواد كانت الإجابة بنعم او لا:

_____

_____

Appendix 8**: Focus group questions guidance (Health coaches)**

Appendix 0-8: Focus group questions guidance (Health coaches)

Health coaches' focus group questions:

Category of question	Sub-category	Questions
Intervention content and delivery	Intervention development	To what degree does the health coaching intervention need to be enhanced or modified to be more acceptable to users or relevant or valuable to the unique environment in which it is delivered?
	Perceived value, benefits, harms or unintended consequences of the intervention	What benefits and harms do you believe you have experienced from the intervention, and how might harm be avoided in the full trial?
	Acceptability of intervention in principle	Are there any aspects of the intervention's content or delivery that intervention users or healthcare providers find to be problematic?
	Feasibility and acceptability of intervention in practice	What do healthcare providers or intervention users think about how the intervention is being carried out? Has there been a difference in how it has been implemented depending on the environment? Do the intervention and the context have any significant interactions? Should implementation differ depending on the setting?
	Fidelity, reach and dose of intervention	Is the appropriate dosage of the intervention appropriately reaching the proper recipients? Follow-through with the intended intervention is there among those delivering it and/or receiving it? What are the causes of this, if not? What are the limits for ?appropriate intervention customization
Trial design, conduct and processes	Recruitment and retention	How do the proposed recruiting procedures function in practice, given the COVID-19 restrictions? Do better recruitment procedures need to be implemented in order to boost recruitment rates and levels of informed consent? Are recruiters keen to find new patients, or do they feel awkward doing so? Are there techniques to enhance trial processes in order to improve retention rates?
	Diversity of participants	Are there any chances that the study will enrol the intended range of individuals as a consequence of the planned recruiting ?strategies? If not, how may recruitment procedures be improved? Participants age

Category of question	Sub-category	Questions
	Trial participation	How are recruiters carrying out and participants responding to the planned trial communication? What can be done to guarantee that trial recruiters know the patients' views towards participating in the study?
	Acceptability of the trial in principle	Is the intervention design generally regarded as acceptable by participants, recruiters, and service providers?
	Acceptability of the trial in practice	In practice, is the trial design well-received by patients, recruiters, and service providers, or do participants attempt to modify the procedures?
	Adaptation of trial conduct to local context	Do the proposed trial procedures enable effective operation in the intended context, and are any adjustments necessary during the trial's implementation?
	Impact of trial on staff, researchers, participants and the health system	Are there any unforeseen adverse effects of this trial on the health system, participants, or recruiters?
Outcomes	Breadth and selection of outcomes	Did the trial measure outcomes that are important to service users, including primary and secondary outcomes? Do some participants feel that they have experienced improvements in certain outcomes that should be included in the full trial?
Measures	Accuracy of measures	Do the process and outcome measures hold validity for this group of participants?

Focus group questions guidance (Participants)

Understanding participants' experiences with the health coaching using COM-B and TDF.

Warm-up:

How does living with diabetes feel like?

Probe: Eating healthy and exercising, monitoring glucose levels, and taking medications.

Exploring Capability:

2. How do you feel about your diabetes knowledge (diet and physical activity)? What needs to change?

- Do you think your lifestyle or diet caused your diabetes?
- Probe: Do you feel like it was inevitable, or you couldn't do anything about it?
- What stops you from adopting a healthy lifestyle (diet and physical activity)?
- What helped you make changes to your lifestyle?
- What do diabetics need after diagnosis?

Preferences for Receiving Health Information:

- Who do you trust most to give you diabetes-related information?

If you need help understanding diabetes information, who do you go to for clarification?

- What is the physician's role in this?

Probe: Do they give you enough time to discuss your condition?

Exploring Opportunity:

- How does your social network influence your condition?

Probe: Stress and support.

- What changes in your social network or family could make it easier for you to adopt a healthy lifestyle?
- How would you describe your living environment?

Probe: Resources, sidewalks, parks, gyms, markets, fast-food restaurants.

Exploring Motivation:

- How can we help people overcome negative social barriers, like eating with their hands or accepting extra food?

Intervention Characteristics:

- During COVID-19, we used online communication. Should we continue this for future programs?
- Who is the best person to conduct health coaching?

Probe: Trained local people? Gender of health coach?

- The program lasts three months, with two sessions each week. What do you think?

Probe:

- Are people willing to do this?
- Is this too much?
- Is this enough to change people's lifestyles?
- Why do you think people would drop out?
- Do you think the program would fit into people's lives?

Outer Setting:

- Which physical activities are the most popular? Walking? Biking? Fitness classes?
- Where do people usually exercise? At home? Gym? Outside?
- Would using a daily tracker (e.g., watch) encourage people to be more active?

Inner Setting:

- What is the best way to recruit diabetics? How should we advertise?
- Should we conduct an orientation before the program?

- What do you think about the health coaching you received during the intervention? Content? design?
- What were your expectations before you started?
- How would you describe your self-management role after receiving health coaching?
- What are the main differences you notice between health coaching and the regular care you receive in the past?
- What are the most important features of health coaching that help you to adopt a healthy lifestyle?
- Do you think health coaching feasible to apply and fits the Saudi context? Why?
- What suggestions would you give to improve the health coaching program?
- How satisfied are you with the program?

Effects of Health Coaching:

- Can you describe one of the sessions you had with the health coach?
- Can you tell me about any changes you made during the health coaching?
- Are you thinking of making any changes now?

Outcomes:

- Do you feel different about your health now?
- What effect have any changes you made had on your body?

Questions to explore patients' experience with T2DM

1. In your opinion, what does a healthy person look like?
2. How would you describe your diabetes related knowledge, including the role of physical activity and diet?
3. What diabetes-related information you rely on or follow to manage your diabetes?
4. How would you describe your routine visits to your doctor? To what extent those visits help you with your diabetes?
5. How would you describe your life living with diabetes?
6. How would you describe the surrounding environment in terms of positive or negative impacts on your diabetes?
7. How would you describe your diabetes management to control the disease?
8. How would you describe the changes in your lifestyle, including behaviours after being diagnosed with T2DM?
9. How would you see the role of (non-medication) adopting a healthy lifestyle to control the disease?
10. What alternatives do you see that would work effectively to control diabetes?
11. Why it seems difficult for some people with diabetes to effectively maintain a healthy lifestyle, including daily exercise and a healthy diet?
12. What barriers prevent you from doing physical activity and eating healthy?
13. What motivators encourage you to do physical activity and eating healthy?

Questions to explore patients' experience with health coaching intervention

1. How would you describe your perceptions and expectations about health coaching before you started this intervention?
2. How would you describe your experience with the health coaching you have received in this intervention?
3. Can you tell me about any changes you made regarding your diabetes after receiving health coaching?
4. Do you think that you have achieved good outcomes and feel different now? How?
5. How would you describe your self-management role after receiving health coaching?
6. What are the main differences you notice between health coaching and the regular care you receive in the past?
7. What are the most important features of health coaching that help you to adopt a healthy lifestyle?
8. Do you think health coaching feasible to apply and fits the Saudi context? Why?
9. What suggestions would you give to improve the health coaching program?
10. What would you say if someone with T2DM or other chronic disease asks you about health coaching?

Appendix 9: **Interview Guide questions**

أسئلة تخص مرحله ماقبل الدخول في البرنامج

1. كيف تصف معرفتك (ثقافتك) المتعلقة بمرض السكري (النظام الغذائي والنشاط البدني)؟
2. ما هو مصدر المعلومات الذي تعتمد عليه؟
3. هل تشعر أن نمط الحياة أو النظام الغذائي كان هو السبب في اصابتك بمرض السكري؟
4. ما هي العوائق التي كانت تمنعك من اتباع أسلوب حياة صحي (نظام غذائي ونشاط بدني)؟
5. كيف تصف زياراتك الروتينية لطبيبك؟ الوقت الذي تقضيه في العيادة ،مفيد؟ داعم؟ او غير ذلك؟
6. كيف تصف البيئة المحيطة بك (الاجتماعية) من حيث انها إيجابية أو سلبية للتحكم بالسكري؟ مثل: تحضير الوجبات ، الاكل مجاملة، ممارسة الرياضه؟ ، ....
7. كيف تصف قوة إرادتك للسيطرة على مرض السكري لديك؟
8. ماهو الحافز الرئيسي لممارسه الرياضه والاهتمام بالتغذية الصحيه؟

أسئلة مابعد تطبيق البرنامج؟

1. إلى أي مدى أدى البرنامج إلى زيادة معرفتك (ثقافتك) المتعلقة (النظام الغذائي والنشاط البدني)؟
2. ما هو الشيء الرئيسي الذي تعلمته للتدخل؟
3. ما هي أهم الفروق التي تلاحظها بين برنامج التدريب الصحي والرعاية التي تتلقاها في الماضي ((usual care؟
4. كيف كانت توقعاتك (نظرتك) للبرنامج قبل أن تبدأ البرنامج؟ وكيف هو شعورك حاليا؟
5. صف كيف وجدت برنامج التدريب الصحي التالي؟ سهل / صعب؟
6. هل أثر البرنامج على عاداتك الغذائية اليومية وممارسة الرياضه؟
7. هل تعتقد أنك حققت نتائج جيدة وتشعر بالفرق الآن ؟ كيف؟
8. كيف تصف دور "ادارتك الذاتية" للسكري بعد تلقي البرنامج؟
9. هل تعتقد أن التدريب الصحي يناسب السياق السعودي (مجتمعا)؟

10. ما رأيك في تنفيذ طريقة تنفيذ التدريب الصحي ؟ عدد الجلسات ، مده الجلسات، مده البرنامج ، طريقه التواصل (تفضل حضورياً او بالاتصال عن بعد.....)
11. هل تعتقد أنك راضي عن البرنامج وترى انه مقبول كما هو الآن لتطبيقه مره اخرى؟
12. ما هي الاقتراحات التي تقدمها لتحسين برنامج التدريب الصحي؟
13. هل لديك أي ملاحضات على البرنامج ؟
14. هل توصي بهذا البرنامج للآخرين الذين يعانون مرض السكري بالانضمام له لاحقاً؟

Appendix 10: Health coaching intervention curriculum

Appendix 0-10:Health coaching intervention curriculum

Core Competencies	How it Connects
A. Foundation	**1. Demonstrates Ethical Practice:** Definition: Understands and consistently applies coaching ethics and standards of coaching **2. Embodies a Coaching Mindset:** Definition: Develops and maintains a mindset that is open, curious, flexible, and client-centred.
B. Co-Creating the Relationship	**3. Establishes and Maintains Agreements:** Definition: Partners together with the client and relevant stakeholders to create clear agreements about the coaching relationship, process, plans, and goals. Establishes agreements for the overall coaching engagement as well as those for each coaching session. **4. Cultivates Trust and Safety:** Definition: Partners together with the client to create a safe, supportive environment that allows the client to share freely. Maintains a relationship of mutual respect and trust. **5. Maintains Presence:** Definition: Is fully conscious and present with the client, employing a style that is open, flexible, grounded, and confident
C. Communicating Effectively	**6. Listens Actively:** Definition: Focuses on what the client is and is not saying to fully understand what is being communicated in the context of the client systems and to support client self-expression **7. Evokes Awareness:** Definition: Facilitates client insight and learning by using tools and techniques such as powerful questioning, silence, metaphor or analogy
D. Cultivating Learning and Growth	**8. Facilitates Client Growth** Definition: Partners with the client to transform learning and insight into action. Promotes client autonomy in the coaching process.

The **Four behaviour targets** (Moore et al., 2019):

- Decrease carbohydrate intake for each meal
- Use unsaturated fats where possible (avoid saturated fats)
- Do exercise for 30 min, five days on a weekly basis
- Monitor waist circumference, maintain it below (80 cm for women)

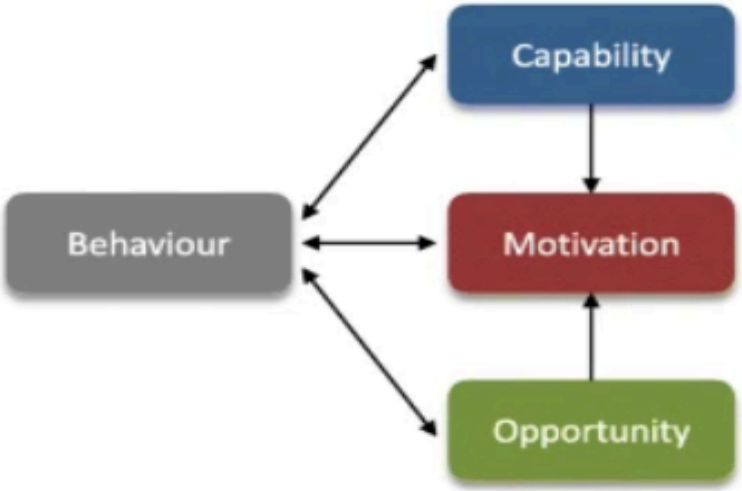
Participants

The target population of this study are adult males and females with T2DM (HbA1c) ≥ 7.0%. Participants will be eligible for recruitment as per the following criteria:

Inclusion and exclusion criteria

1. Aged >18 years old;
2. The participant diagnosed with T2DM as demonstrated by haemoglobin A1c (A1c) ≥ 7.0%;
3. The participant can read and understand Arabic;
4. The participant has access to a personal mobile phone/smartphone;
5. The participant is willing to complete the intervention period;
6. The participant is willing to remain in Riyadh; and
7. The participant can read, understand, and sign the informed consent form

Behaviour Change Wheel (BCW)



Barriers identification:

COM-B		TDF	Barrier	Intervention Function	BCTs
Capability	Psychological	Knowledge	Poor T2DM knowledge affect self-control Poor nutrition knowledge (what the association between diabetes and diet, type of healthy food) Poor knowledge about PA (how to engage in PA, how much time spend on PA, PA intensity, PA types, underestimate the role of PA	Education	5.1Information about health consequences
	Physical	Physical skills	Lack of the energy to do PA Lack or limited skills of physical skills to do exercise	Enablement Training	**Enablement:** 6.1Demonstration of the behaviour 1.5 Review behaviour goal (s) 1.7 Review outcome goal (s) 2.3 Self-monitoring of behaviour 12.1 Restructuring the physical environment 4.1 Instruction on how to perform a behaviour' 3.1 Social support (unspecified) **Training:** 8.1 Behavioural practice/rehearsal 8.3 Habit Formation 8.4 Habit reversal 8.7 Graded tasks 15.4 Self-talk 10.9 Self-reward 2.2 Feedback on behaviour 2.3 Self-monitoring of behaviour

COM-B		TDF	Barrier	Intervention Function	BCTs
Opportunity	Social	Social influences	Social norms & habits: overuse of high calories food intake; carbohydrates and fats, eating together (collectives), and social courtesy to eat unhealthy diet	Enablement	**Enablement**: 1.3 Goal setting (outcome) 1.1 Goal setting (Behaviour) 3.1 Social support (unspecified) 1.4 Action planning 1.2 Problem-solving 2.3 Self-monitoring of behaviour 8.7 Graded tasks 5.5 Anticipated regret 12.1 Restructuring the physical environment 12.2 Restructuring the social environment
	Physical	Environmental context and resources	Lack of time Lack of resources (environmental, appropriate climate & financial ability) Lack of access to do activity Overuse of cars for transportations	Restriction Environmental restructuring Enablement Modelling	**Enablement:** 1.3 Goal setting (outcome) 1.1 Goal setting (Behaviour) 3.1 Social support (unspecified) 1.4 Action planning 1.2 Problem-solving 2.3 Self-monitoring of behaviour 9.2 Pros and cons 9.3 Comparative imagining of future outcomes 8.7 Graded tasks 1.9 Commitment 13.2 Framing/reframing 5.5 Anticipated regret 12.5 Adding objects to the environment **Modelling:** 6.1 Demonstration of the behaviour

COM-B		TDF	Barrier	Intervention Function	BCTs
					Environmental restructuring: 12.1 Restructuring the physical environment 7.1 Prompts/Cues **Restriction:** Use rules to reduce opportunity to engage in unwanted behaviour
Motivation	Reflective	Beliefs about own capability	Lack of willpower and self-confidence to do PA and maintain healthy diet	Persuasion Education Enablement	**Persuasion:** 15.1 Verbal persuasion about capability 15.2 Mental rehearsal of successful performance 9.1 Credible source 2.2 Feedback on behaviour 13.2 Framing/reframing 15.3 Focus on past success **Education:** 5.1 Information about health consequences 5.3 Information about social and environmental consequences **Enablement:** 1.9 Commitment 5.5 Anticipated regret
		Beliefs consequences	Fear from consequences of PA (fear of injury and disease future complications)	Education	5.1 Information about health consequences
		Social role and identity	Struggle to change social identity associated with culture diet Struggle to accept the fact of living with diabetes	Education Persuasion	**Education**: 5.1 Information about health consequences **Persuasion:** 13.5 Identity associated with changed behaviour

Addressing identified barriers

COM-B		TDF coding included in this research	What needs to be occurred to bring about change?			
			Decrease carbohydrate intake in each meal	Use unsaturated fats as possible (avoid saturated fats)	Do exercise for 30 min, five days on a weekly basis	Monitor waist circumference
Capability	Psychological	Knowledge	Knowledge: Understand food types (especially carbohydrate types, e.g., rice and dates) Understand carbohydrate quantity targets Understand alternative food (more fibre) to replace carbohydrate to avoid hunger	Knowledge: Understand food types in terms of fats included Understand unsaturated fats sources Start learning how to cook to take control of meals' components	Knowledge: Understand the role of PA and impacts in simple language Understand how to do exercise (indoor and outdoor) Understand what the most suitable and enjoyable exercise	Knowledge: Understand the associations between waist circumference and T2DM Understand the recommended target of waist size Understand how to maintain a good size
	Physical	Physical skills	How to measure carbohydrate quantity	NA	Have the energy and the required skills to do PA	Taking the measurement frequently for comparison
Opportunity	Social	Social influences	Having social support e.g., family members or friends to stay motivated to change the behaviour Preparing your own meal as possible when you are outside house Explain and kindly refuse any meal would hurt your diet (many dates, rice, sweets…etc.)	Having social support e.g., family members or friends to stay motivated to change the behaviour Preparing your own meal as possible when you are outside house Explain and kindly refuse any meal would hurt your diet e.g., unsaturated fats	Having social support e.g., family members or friends to stay motivated to change the behaviour Meeting people at parks to walk together	Having social support e.g., family members or friends to stay motivated to change the behaviour
	Physical	Environmental context and resources	Avoid eating fast food as possible Buy food that contain more fibre	Avoid eating fast food where possible Buy food that contain unsaturated fats	Register in fitness centre, if possible, to avoid any environmental restrictions Buy essential PA equipment, if possible, to avoid any environmental restrictions Have daily time for PA Do the most suitable and enjoyable exercise	Have a tape to measure waist circumference

COM-B		TDF coding included in this research	What needs to be occurred to bring about change?			
			Decrease carbohydrate intake in each meal	Use unsaturated fats as possible (avoid saturated fats)	Do exercise for 30 min, five days on a weekly basis	Monitor waist circumference
Motivation	Reflective	Beliefs about own capability Beliefs consequences Social role and identity	Beliefs about own capability: Have a willpower and self-confidence in ability to make the change Have alternatives to cope financial incapability Beliefs about consequences: Understand the negative impacts for much carbohydrate intake Understand the risk factors of developing other diseases Social role and identity: Address the social barrier (carbohydrate portion size, find facilitates like using spoon)	Beliefs about own capability: Have a willpower and self-confidence in ability to make the change Have alternative to cope financial incapability Beliefs about consequences: Understand the negative impacts of food contain saturated fats Understand the risk factors of having saturated fats in developing other diseases Social role and identity: Address the social barrier (using unsaturated fats for cooking)	Beliefs about own capability: Have a willpower and self-confidence in ability to do the exercise Beliefs about consequences: Overcome the fears of injury Understand the risk factors of being physically inactive Social role and identity: Address the social barrier (overcome social barriers related to PA)	Change self-view of west circumferences Beliefs about consequences: Understand the significance of accomplishing the waist circumference target

BCTs matching the motivational interviewing, partly adopted from Hardcastle et al., (2017)

MI Technique	Example of Technique	BCTs from Michie et al.'s (2013) taxonomy
ENGAGING TECHNIQUES:		
Affirmation	Despite the fact that things didn't go as you had hoped, your intentions were good."	15.1: Verbal persuasion about capability
FOCUSING TECHNIQUES:		
Elicit-Provide Elicit	"What do you know about type II diabetes? "	5.1: Information about health consequences

EVOKING TECHNIQUES:		
Running Head Start	"What advantages might a change in lifestyle bring?"	9.2: Pros and cons
Looking Forward	"What may occur if the current situation is maintained?"	9.3: Comparative imagining of future outcomes
Hypothetical thinking	"What steps would you take if you did decide to alter your behaviour?"	15.2: Mental rehearsal of successful performance
Query Extremes	"What do you think would be the BEST outcome from this change?"	5.5: Salience of consequences
Identify Past Successes	"What have you discovered after trying to change in the past?"	15.3: Focus on past success
Identify Strengths	"Tell me about your key strengths?"	13.4: Valued self-identity
Troubleshooting	"Imagine supposing there wasn't this one significant roadblock. How might you go about implementing this change if that barrier were removed?"	1.2: Problem-solving
Values Exploration (open or structured)	"What issues are most crucial to you? or "What is your greatest life goal?" How do your eating habits align with your beliefs and goals?"	13.4: Valued self-identity
Reframing	Change "I'm unable to do it" to "So, you find it challenging to…"	13.2: Framing/reframing
Normalizing	"Most people have both positive and negative effects from altering their [target behaviour]" or "Many people report experiencing similar emotions to yours. They try to lose weight, but they have trouble.	6.2: Social comparison
PLANNING TECHNIQUES:		

Explore Change Expectations	“What would you anticipate happening if you choose that course of action?”	1.3: Goal setting (outcome)
Consider Change Options	“What are the things you could do?”	1.4: Action planning
Develop a Change Plan	What do you intend to do specifically?	1.4: Action planning
Goal attainment Scaling	Rate a weight loss goal on a scale ranging from −3 (most unfavourable outcome): gain 5 kg in one month to +3 (most favourable outcome): lose 5 kg in one month where 0 is the status quo (remain at current weight)	1.5: Review behaviour goal(s)
Support Change/Persistence	“How may I help you?”	3.1: Social support (unspecified)
Offer Emotional support	“I can assume that I would feel the same way if I were going through what you are.”	3.3: Social support (emotional)
Review Outcome goal	“How far along are you with your objective?”	1.7: Review outcome goal(s)
Summarise the Plan	“So, you are going to do …”	1.9: Commitment

BCTs matching the stage of change model, partly adapted from Moore et al., (2015)

Stage	Health coaching Skills to use	Matched with BCTs
Pre-contemplation	Empathy	3.3: Social support (emotional)
	Sharing	3.1: Social support (unspecified)
	Acceptance	13.4: Valued self-identity
	Affirming	15.1: Verbal persuasion about capability
	Reframing	13.2: Framing/reframing
	Sorting barriers	1.2: Problem-solving
Contemplation	Affirming	15.1: Verbal persuasion about capability
	Sharing	3.1: Social support (unspecified)
	Brainstorming/Sorting barriers	1.2: Problem-solving
	Motivating	10.2: Social reward 3.1: Social support (unspecified)
	Self-Efficacy and Self-Esteem:	
	Verbal persuasion	15.1: Verbal persuasion about capability 15:4 Self-talk
	Vicarious experience	6.2: Social comparison
Preparation	Committing	1.9: Commitment
	Identifying steps	1.1 Goal setting (behaviour)
	Explore change expectations	1.3: Goal setting (outcome)

	Identifying potential obstacles	1.2: Problem-solving
	Values Exploration	13.4: Valued self-identity
Action	Having a plan	1.4: Action planning
	Reframing	13.2: Framing/reframing
	Tracking progress	1.7: Review outcome goal(s)
	Normalising	6.2: Social comparison
	New network	3.1: Social support (unspecified)
	Preparing for lapses/facing obstacles	1.2: Problem-solving
Maintenance	Maintaining the network	3.1: Social support (unspecified)
	Valuing achievements	9.3: Comparative imagining of future outcomes
	Self-identity	13.1: Identification of self as a role model

Selected BCTs for use in this study

No.	Use OR Not	Lable	Definition	Examples
1.		**1.1 Goal setting (Behaviour)**	Set or agree on a goal defined in terms of the behavior to be achieve	Agree on a daily walking goal (e.g. 3 miles) with the person and reach agreement about the goal Set the goal of eating 5 pieces of fruit per day as specified in public health guidelines
2.		**1.2 Problem-solving**	Analyse , or prompt the person to analyse, factors influencing the behavior and generate or select strategies that include overcoming barriers and/or increasing facilitators (includes '**Relapse Prevention**' *and* '**Coping Planning**')	Identify specific triggers (e.g. being in a pub, feeling anxious) that generate the urge/want/need to strategies for avoiding environmental triggers or for managing negative emotions, such as anxiety Prompt the patient to identify barriers preventing them from starting a new exercise regime e.g., l discuss ways in which they could help overcome them e.g., going to the gym with a buddy
3.		**1.3 Goal setting (outcome)**	Set or agree on a goal defined in terms of a positive **outcome** of wanted behavior	Set a weight loss goal (e.g. 0.5 kilogram over one week) as an outcome of changed eating pattern
4.		**1.4 Action planning**	Prompt detailed planning of performance of the behavior (must include at least one of context, frequency, duration and intensity). Context may be environmental (physical or social) or internal (physical, emotional or cognitive) (includes '**Implementation Intentions**')	Encourage a plan to carry condoms when going out socially at weekends Prompt planning the performance of a particular physical activity (e.g. running) at a particular tim certain days of the week
5.		**1.5 Review behaviour goal (s)**	Review behavior goal(s) jointly with the person and consider modifying goal(s) or behavior change strategy in light of achievement. This may lead to re-setting the same goal, a small change in that goal or setting a new goal instead of (or in addition to) the first, or no change	Examine how well a person's performance corresponds to agreed goals e.g. whether they consum alcohol per day, and consider modifying future behavioral goals accordingly e.g. by increasing or target or changing type of alcohol consumed
6.		**1.7 Review outcome goal (s)**	Review outcome goal(s) jointly with the person and consider modifying goal(s) in light of achievement. This may lead to re-setting the same goal, a small change in that goal or setting a new goal instead of, or in addition to the first	Examine how much weight has been lost and consider modifying outcome goal(s) accordingly e.g decreasing subsequent weight loss targets
7.		**1.9 Commitment**	Ask the person to affirm or reaffirm statements indicating commitment to change the behavior	Ask the person to use an "I will" statement to affirm or reaffirm a strong commitment (i.e. using t "committed" or "high priority") to start, continue or restart the attempt to take medication as pres
8.		**2.2 Feedback on behaviour**	Monitor and provide informative or evaluative feedback on performance of the behavior *(e.g. form, frequency, duration, intensity)*	Inform the person of how many steps they walked each day (as recorded on a pedometer) or how each day (based on a food consumption questionnaire).
9.		**2.3 Self-monitoring of behaviour**	Establish a method for the person to monitor and record their behavior(s) as part of a behavior change strategy	Ask the person to record daily, in a diary, whether they have brushed their teeth for at least two m bed Give patient a pedometer and a form for recording daily total number of steps
10		**3.1 Social support (unspecified)**	Advise on, arrange or provide social support *(e.g. from friends, relatives, colleagues,' buddies' or staff)* or non- contingent praise or reward for performance of the behavior. It includes	Advise the person to call a 'buddy' when they experience an urge to smoke

			encouragement and counselling, but only when it is directed at the **behavior**	Arrange for a housemate to encourage continuation with the behavior change programme Give information about a self- help group that offers support for the behavior
11		**4.1 Instruction on how to perform a behaviour'**	Advise or agree on how to perform the behavior (includes '**Skills training**')	Advise the person how to put a condom on a model of a penis correctly
12		**5.1Information about health consequences**	Provide information (e.g. written, verbal, visual) about health consequences of performing the behavior	Explain that not finishing a course of antibiotics can increase susceptibility to future infection Present the likelihood of contracting a sexually transmitted infection following unprotected sexua
13		**5.5 Anticipated regret**	Induce or raise awareness of expectations of future regret about performance of the unwanted behavior	Ask the person to assess the degree of regret they will feel if they do not quit smoking
14		**5.3 Information about social and environmental consequences**	Provide information (e.g. written, verbal, visual) about social and environmental consequences of performing the behavior	Tell family physician about financial remuneration for conducting health screening Inform a smoker that the majority of people disapprove of smoking in public places
15		**6.1Demonstration of the behaviour**	Provide an observable sample of the performance of the behaviour, directly in person or indirectly e.g. via film, pictures, for the person to aspire to or imitate (includes '**Modelling**').	Demonstrate to nurses how to raise the issue of excessive drinking with patients via a role- play e
16		**8.1 Behavioural practice/rehearsal**	Prompt practice or rehearsal of the performance of the behavior one or more times in a context or at a time when the performance may not be necessary, in order to increase habit and skill	Prompt asthma patients to practice measuring their peak flow in the nurse's consulting room
17		**8.3 Habit Formation**	Prompt rehearsal and repetition of the behavior in the same context repeatedly so that the context elicits the behavior	Prompt patients to take their statin tablet before brushing their teeth every evening
18		**8.4 Habit reversal**	Prompt rehearsal and repetition of an alternative behavior to **replace** an unwanted habitual behavior	Ask the person to walk up stairs at work where they previously always took the lift
19		**9.1 Credible source**	Present verbal or visual communication from a **credible source** in favour of or against the behavior	Present a speech given by a high status professional to emphasise the importance of not exposing radiation by ordering x-rays for back pain
20		**9.2 Pros and cons**	Advise the person to identify and compare reasons for wanting (pros) and not wanting to (cons) change the behavior (includes '**Decisional balance**')	Advise the person to list and compare the advantages and disadvantages of prescribing antibiotics tract infections
21		**9.3 Comparative imagining of future outcomes**	Prompt or advise the imagining and comparing of future outcomes of changed versus unchanged behaviour	Prompt the person to imagine and compare likely or possible outcomes following attending versu screening appointment
22		**10.9 Self-reward**	Prompt self-praise or self-reward if and only if there ***has been*** effort and/or progress in performing the behavior	Encourage to reward self with material (e.g., new clothes) or other valued objects if and only if th healthy diet
23		**12.1 Restructuring the physical environment**	Change, or advise to change the **physical** environment in order to facilitate performance of the wanted behavior or create barriers to the unwanted behavior (other than prompts/cues, rewards and punishments)	Advise to keep biscuits and snacks in a cupboard that is inconvenient to get to Arrange to move vending machine out of the school

24		**12.2 Restructuring the social environment**	Change, or advise to change the **social** environment in order to facilitate performance of the wanted behavior or create barriers to the unwanted behavior (other than prompts/cues, rewards and punishments)	Advise to minimise time spent with friends who drink heavily to reduce alcohol consumption
25		**12.5 Adding objects to the environment**	Add objects to the environment in order to facilitate performance of the behavior	Provide free condoms to facilitate safe sex Provide attractive toothbrush to improve tooth brushing technique
26		**13.2 Framing/reframing**	Suggest the deliberate adoption of a perspective or new perspective on behavior (e.g. its purpose) in order to change cognitions or emotions about performing the behavior	Suggest that the person might think of the tasks as reducing sedentary behavior (rather than increa
27		**13.5 Identity associated with changed behaviour**	Advise the person to construct a new self- identity as someone who 'used to engage with the unwanted behavior'	Ask the person to articulate their new identity as an 'ex-smoker'
28		**15.1 Verbal persuasion about capability**	Tell the person that they can successfully perform the wanted behavior, arguing against self-doubts and asserting that they can and will succeed	Tell the person that they can successfully increase their physical activity, despite their recent hear
29		**15.2 Mental rehearsal of successful performance**	Advise to practise imagining performing the behavior successfully in relevant contexts	Advise to imagine eating and enjoying a salad in a work canteen
30		**15.3 Focus on past success**	Advise to think about or list previous successes in performing the behavior (or parts of it)	Advise to describe or list the occasions on which the person had ordered a non-alcoholic drink in

Intervention operation protocol

Phase #	*Session Content*	*Session Goals*	*Intervention function*
1	• Session #1, the patient's assessment form and consent supposed to be completed • General introduction about the health coaching intervention • Outline the intervention structure and content • Discuss the coach's roles and the expectations from the participant (being completely clear with the client about the health coaching) • Creating an alliance (Establish Trust) • Learn from a patient (diseases history, obstacles, priorities, strengths, goals... etc) • Help patient to create wellness vision • Assess the readiness of patient's stage in relation to change health behaviour (the transtheoretical model) • Introduce the importance of having a healthy diet • Introduce the importance of increasing physical activity • Increase awareness of adopting a healthy lifestyle in relation to controlling diabetes • Identify 3-month general behavioural goals, and biweekly goals • Explore resources needed to help achieve desirable behaviour • Commitment	• Identifying the patient's current position in the overall health status (via the transtheoretical model) • Build up a relationship (as an ally) between patient and coach • Encourage open discussion • Make sure the patient understands what health coaching is • Allow the patient to develop a foundational conception of goal setting and action planning • The patient creates (SMART) Specific, Measurable, Action-based, Realistic and Timely achievable goals • Have better control of carbohydrate and fat intake • Gradually increase physical activity • Gradually increase achievable tasks until the intended behaviour is achieved	• Education • Enablement • Training • Restriction • Environmental restructuring
2	• Phase #2 (session # 2), (this phase will be used again in session # 4 & 5) • Check ongoing progresses • Understand patient's state (use reflections) • Ask patient to share views (so far) good things occurred and experience from last session • Use positive reflections about patient's strengths, passion, or emotions • Ask patient to assess the previous selected short-goals and accomplishments • Use reflections to understand potential barriers prevent patient from achieving past goals • Identify specific strategies that they may use to overcome the obstacles • Explore what patient learned from past experience	• Assessment of progression • Review goal setting (behaviour) • Review behaviour goals to examine a patient's performance progression toward the agreed goals • Enable patient to develop problem-solving skills • Enable patient to create action plan • Prompt the participant to generate ideas and strategies to overcome barriers (problem-solving) • Allow patients to monitor their behaviours (know the changes so far) • Keep patient motivated (no matter the accomplishments)	• Persuasion • Education • Enablement • Training • Restriction • Environmental restructuring

	• Ask and discuss with patient next short goals • Share feedback on patient's progression • Ask patient to connect current accomplishments to the general 3-months goals • Review the general goals to see if patient want to revise them (to be more realistic and achievable) • Affirm the patient's choices, strengths, and capability • Use techniques such as reflective listening to address ambivalence and respond to the patient's resistance (motivational interviewing)		
3	• Middle phase (session # 3), the coach continues to observe the patient and give feedback to help them move forward in achieving their goals through bi-weekly SMART goal setting. • Patient continues to identify strategies to address existing obstacles and enhance their self-ability • If goals are not achieved, the barriers will be identified, action plan will be taken to address these obstacles and modified goals will be created. • The coach will assess the patient's self-efficacy by scoring goals to measure the participant's confidence in achieving their goals • The coach continues using the skills needed to explore ambivalence and discrepancies between the participant's plans and their actual behaviour (Rollnick et al, 2005) • Affirmations and appreciative inquiry will be used to appreciate progression and improve patients' self- confidence	• Assessment of current behavioural change • Review goal setting (behaviour) • Review behaviour goals to examine a patient's performance progression toward the agreed goals • Review all previous goals and reassess goal progress • Enable the participant to assess their progress • Prompt the participant to analyse factors influencing their behaviour • Participant's commitment to affirm to review and change behaviour	• Persuasion • Education • Enablement • Training
4	• (Session # 6) • Conclude the coaching relationship • Determine where the patient is in terms of their goals • How the coach can best guide the client, and whether coaching is what will best benefit the client • Participants' assessment of the intervention, general satisfaction of the participant with the process • Appreciate the patient's engagement in the intervention • Explore the patients' experience and how future coaching intervention would best support T2DM	• Allow patient to explore the difference at the endpoint • Learn for participants' experience • Findings from the pilot study will be used to justify an expansion of the study (full-scale) or refined for better outcomes so that we can carry out a large RCT on the efficacy of this intervention	• Persuasion • Education

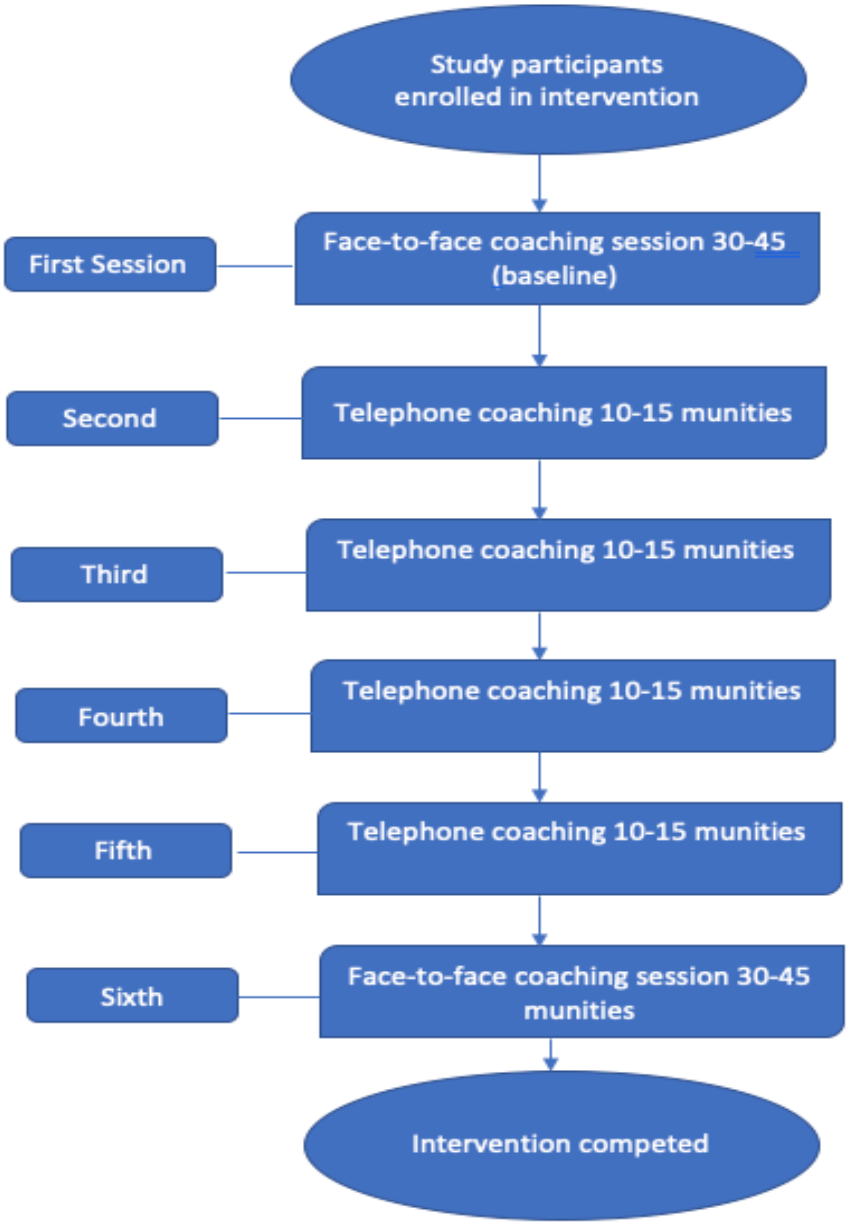
Weekly coaching sessions (weekly, biweekly, or monthly) (Wellcoaches, 2009) [112]

	Action BEFORE THE SESSION
	Review notes from previous session(s)
	Practice Mindfulness
	Remember the key coaching skills: Mindful Listening, Inquiry and Reflection Formulate initial, strengths-based inquiries
	SESSION OPENING
	Asks how the client is right now "in this moment."
	Uses reflections to show understanding of client's state.
	Asks the client to share the best thing that happened from previous week(s) Reflects something positive about the client (e.g., highlights, strengths, or emotions) Asks client to select the first weekly goal to be discussed
	WEEKLY GOAL REVIEW
	Explores full experience with weekly goal, starting with the positive
	Uses reflections to show listening and understanding of the goal experience Expands inquiry about the client's best experience with his/her weekly goal Responds to client challenges with judgment-free reflections and inquiries Asks what the client learned from his/her experience
	Affirms the client: strengths, choices, and/or situation
	Inquiries about the client's percentage of success
	THREE-MONTH GOAL REVIEW
	Validates the relevance of the client's Wellness Vision and connection to three-month goals Asks about the client's best learning or growth experience with his/her three-month goals
	Asks about the client's level of commitment with his/her goals and whether he/she wants to revise them
	Affirms the client's strengths, abilities, or growth.

	GENERATIVE MOMENT
	Collaborates with the client to identify the topic to work on, where he/she has aroused emotional energy and interest
	Asks for permission to explore and work on the topic now
	Encourages the client to describe what he/she really wants now, in relation to the topic
	Explores the strengths or values the client can leverage to move forward
	Explores the environments the client can leverage to move forward
	Explores decisional balance and develops discrepancy when the client demonstrates ambivalence
	Engages the client in creative brainstorming of pathways forward
	Expresses confidence in the client's ability to move forward
	GOAL SETTING
	Asks the client to choose a goal that is important and that he/she is ready to pursue
	Explores the support, structure, or environments needed to ensure success and handle challenges
	Assists the client to refine goal to be a SMART behavioural goal
	Uses confidence ruler to improve the client's confidence in reaching that goal
	Asks client to restate goals
	Affirms client's ability to achieve his/her goals
	SESSION CLOSE
	Communicates an appreciation of the client's work in the session
	Discovers and reflects what the client learned in the session
	Asks for feedback on how future coaching sessions would best support client's path
	Schedule next session

Initial Coaching Session Checklist (Wellcoaches, 2009) [112]

	BEFORE THE SESSION
	Review the Assessment: Seek out success, notice areas with heightened arousal, consider stages of change, question gaps, note concerns
	Practice Mindfulness Remember to use the key coaching skills: Mindful Listening, Inquiry and Reflection Formulate initial, strengths-based inquiries
	SESSION OPENING
	Welcome and thank you Thank client for completing an assessment
	Introduction of Coach: Share personal passion, credentials, and experience if not already completed in a prior consultation
	Review and get agreement on the Session Agenda: confirm client expectations and priorities, gather additional information, create vision, design goals
	EXPECTATION SETTING (if not done in a prior consultation)
	What is coaching Confidentiality Record keeping Establish Coaching Contract
	DISCUSS ASSESSMENT
	Find something positive to share from the client's assessment Ask client what s/he learned about him/herself by completing the assessment Ask client what questions s/he has after completing the assessment Gather missing information Discuss client's medical history and need for physician release, if applicable
	CREATE A VISION
	Explain the value of creating a vision Ask what is most important to the client right now
	Collaborate to identify the client strengths: Review success stories, discuss what is working now, discover what gives the client pride
	Discover the client's motivators: ask about the benefits of making changes now, ask about the driving force behind the desire to change now
	Ask about the client's vision (hopes, wishes and dreams) for health, fitness, or
	wellness
	Support the client in visualizing his/her vision and describing it in detail
	Use confidence ruler to assess and improve self-efficacy
	Ask what challenges would be met and what things would be possible if the vision were a reality
	Discover previous positive experiences with elements of the vision Identify the strengths and values that could be used to reach the vision
	Explore the support (people, resources, systems, and environments) needed to ensure success and handle challenges
	Ask the client to state and commit to the vision
	DESIGN THREE-MONTH GOALS
	Explain the nature and value of setting three-month goals Brainstorm consistent behaviors that would lead to the achievement of the vision Ask the client to choose several behavioral goals that are most important to pursue Confirm the connection of the behaviors to the vision Assist the client in developing SMART behavioral goals
	DESIGN FIRST WEEK'S GOALS
	Ask the client to choose goals that are important next steps toward three month behavioral goals
	Assist the client in designing SMART behavioral goals Use confidence ruler to improve the client's confidence in reaching the goal
	Explore the client's strengths and support (people, resources, systems, and environments) needed to ensure success and handle challenges
	Ask the client to restate and commit to SMART goals
	Affirm the client's ability to achieve the goals
	SESSION CLOSE
	Express appreciation for the client's work
	Discover and reflect what the client learned
	Confirm that the client is ready, confident, and committed to take agreed upon actions.
	Ask for feedback on how future coaching sessions would best support the client's path
	Schedule the next session



Health coaching intervention sessions by month

Timeline for the assessment of variables

Study Timeline				
Pre-study allocation			Post-study allocation	
Activity	Enrolment	Allocation	Baseline	Endpoint
Intervention advertising				
Screening eligibility				
Informed consent				
Baseline measures				
Randomization				
Allocation				
Start of the Study:				
Intervention group			→	
Control group			→	
Assessments for both groups				
Demographic				
BMI				
Weight				
Blood pressure				
Waist circumference				
HbA1c				
Feasibility Questionnaires for both groups (pre-and post-intervention)				

Summary of Diabetes Self Care Activity (SDSCA), 12-items				
Self-efficacy Scale for Diabetes, 8-items				
Acceptability Questionnaire for only intervention group (post-intervention)				
Likert Scale Satisfaction Questionnaire, 14-items				
Measures for only intervention group				
Focus groups			→	
Interviews			→	
Field notes and session recordings			→	

Data Collection Checklist

Participant no: _____

☐ Consent (Date: _____)

Baseline:

☐ Demographics (Date: _____)
☐ Questionnaires: (SDSCA) & Self-efficacy Scale (Date: _____)
☐ Body Assessments: BMI, Weight, Waist circumference, Blood pressure, HbA1c (Date: _____)
☐ Randomization (Group: Intervention/Control)

□ Focus Group (Pre-intervention) (Date: _____)

□ Interviews (5 interviews) (Date: _____)

□ Field notes and session

Endpoint: 3 Month

☐ Questionnaires: (SDSCA), Self-efficacy Scale & Satisfaction Questionnaire (Date: _____)
☐ Body Assessments: BMI, Weight, Waist circumference, Blood pressure, HbA1c (Date: _____)

□ Focus Group (Post-intervention) (Date: _____)

□ Interviews (5 interviews) (Date: _____)

Data Collection Form

Participant no: _____

	Baseline	3 Month
Age		
Gender		
Height		
Weight		
BMI		
Waist Cir. (cm)		
HbA1c		
Blood pressure		

Client's Weekly Tracker

Week _____

Desired Change 1. _____

Desired Change 2._____

Action Steps What I agree to do this week	**Sun**	**Mon**	**Tues**	**Wed**	**Thur**	**Fri**	**Sat**	**Progress Notes**
1.								
2.								
3.								
4.								

Challenges	**Successes**
What I would like to focus on in the next coaching session	

Coach Notes

Name	**Date**
Client commitment/agreement from previous session (taken from last week's progress notes)	
Progress Notes	
Challenges	**Opportunities**
Client commitment/agreement for next session: ***Client's confidence level:***	
Challenges as a coach:	

سجل جلسات التدريب

المريض:

المدرب الصحي:

جدول الجلسات

الجلسة الأولى	
الجلسة الثانية	
الجلسة الثالثة	
الجلسة الرابعة	
الجلسة الخامسة	
الجلسة السادسة	

اهدافي بعد ثلاثة أشهر

ما يخص ممارسة الرياضة	
الهدف	
ملاحظات	
اولوياتي:	الإنجاز %:

رؤيتي للصحة هي

محفزاتي

عقباتي هي

استراتيجياتي للتغلب على عقباتي هي

ما يخص التغذية	
الهدف	
ملاحظات	
اولوياتي:	الإنجاز %:

ما يخص الأهداف ذات الصلة	
الهدف	
ملاحظات	
اولوياتي:	الإنجاز %:

ما يخص الأهداف ذات الصلة
الهدف

ملاحظات	
اولوياتي:	الإنجاز %:

ما يخص الأهداف ذات الصلة	
الهدف	
ملاحظات	
اولوياتي:	الإنجاز %:

الأهداف حتى الجلسة القادمة (الجلسة رقم:)

ما يخص (ممارسة الرياضة، التغذية، الأهداف ذات الصلة)	
الهدف	
ملاحظات	
اولوياتي:	الإنجاز % :

ما يخص (ممارسة الرياضة، التغذية، الأهداف ذات الصلة)	
الهدف	
ملاحظات	
اولوياتي:	الإنجاز %:

ما يخص (ممارسة الرياضة، التغذية، الأهداف ذات الصلة)	
الهدف	
ملاحظات	
اولوياتي:	الإنجاز %:

Used BCTs in this session:

Coaching tools: English version

Coaching Log

Client:	
Coach:	

Session Schedule

Session 1:	
Session 2:	
Session 3:	

Wellness Vision

My wellness vision is ...
My motivators are ...
My obstacles are ...
My strategies to overcome my obstacles are ...

Three Month Goals

Month Started:	

Section (Fitness, Nutrition, Stress, Weight, Health, Other):	
Goal:	
Comments:	
Priority:	**Completed %:**

Section (Fitness, Nutrition, Stress, Weight, Health, Other):	
Goal:	
Comments:	
Priority:	**Completed %:**

This Week's Goals: Week 1

Date Goals Set:	

Section (Fitness, Nutrition, Stress, Weight, Health, Other):	
Goal:	
Comments:	
Priority:	**Completed %:**

Section (Fitness, Nutrition, Stress, Weight, Health, Other):	
Goal:	
Comments:	
Priority:	**Completed %:**

Appendix 11: Participants' mean differences in each group at baseline and endpoint for patients' self-efficacy questionnaire

Appendix 0-11:Participants' mean differences in each group at baseline and endpoint for patients' self-efficacy questionnaire

					An independent two-sample t-test			
	Group	N	Mean	Std. Deviation	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
How confident do you feel that you can eat your meals every 4 to 5 hours every day, including breakfast every day? (At the baseline)	Intervention	14	5.36	3.296	.445	.757	-1.249	2.763
	Control	15	4.60	1.805				
How confident do you feel that you can eat your meals every 4 to 5 hours every day, including breakfast every day? (At endpoint)	Intervention	14	7.21	2.082	.505	.481	-.981	1.943
	Control	15	6.73	1.751				
How confident do you feel that you can follow your diet when you have to prepare or share food with other people who do not have diabetes? (At the baseline)	Intervention	14	5.29	3.688	.891	.152	-2.114	2.419
	Control	15	5.13	2.100				
How confident do you feel that you can follow your diet when you have to prepare or share food with other people who do not have diabetes? (At endpoint)	Intervention	14	8.07	1.979	.274	.871	-.732	2.474
	Control	15	7.20	2.210				
How confident do you feel that you can choose the appropriate foods to eat when you are hungry (for example, snacks)? (At the baseline)	Intervention	14	6.07	3.174	.569	.538	-1.379	2.455
	Control	15	5.53	1.685				
How confident do you feel that you can choose the appropriate foods to eat when you are hungry (for example, snacks)? (At endpoint)	Intervention	14	8.21	2.082	.144	1.014	-.368	2.397
	Control	15	7.20	1.521				
How confident do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week? (At the baseline)	Intervention	14	6.50	3.632	.217	1.500	-.936	3.936
	Control	15	5.00	2.726				
How confident do you feel that you can exercise 15 to 30 minutes, 4 to 5	Intervention	14	9.14	1.994	.006	2.276	.713	3.839

times a week? (At endpoint)	Control	15	6.87	2.100				
How confident do you feel that you can do something to prevent your blood sugar level from dropping when you exercise? (At the baseline)	Intervention	14	6.71	3.148	.072	1.848	-.178	3.873
	Control	15	4.87	2.100				
How confident do you feel that you can do something to prevent your blood sugar level from dropping when you exercise? (At endpoint)	Intervention	14	8.71	2.054	.000	3.048	1.493	4.602
	Control	15	5.67	2.024				
How confident do you feel that you know what to do when your blood sugar level goes higher or lower than it should be? (At the baseline)	Intervention	14	5.71	2.867	.616	.448	-1.360	2.256
	Control	15	5.27	1.792				
How confident do you feel that you know what to do when your blood sugar level goes higher or lower than it should be? (At endpoint)	Intervention	14	8.36	2.023	.006	2.157	.678	3.636
	Control	15	6.20	1.859				
How confident do you feel that you can judge when the changes in your illness mean you should visit the doctor? (At the baseline)	Intervention	14	6.93	2.786	.284	.995	-.872	2.862
	Control	15	5.93	2.086				
How confident do you feel that you can judge when the changes in your illness mean you should visit the doctor? (At endpoint)	Intervention	14	9.43	1.016	.000	3.295	2.075	4.516
	Control	15	6.13	1.995				
How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do? (At the baseline)	Intervention	14	5.93	3.125	.660	.462	-1.668	2.592
	Control	15	5.47	2.446				
How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do? (At endpoint)	Intervention	14	8.86	2.033	.006	2.590	.826	4.355
	Control	15	6.27	2.549				

Appendix 12: Participants' mean differences in each group at baseline and endpoint for diabetes self-care activity questionnaire

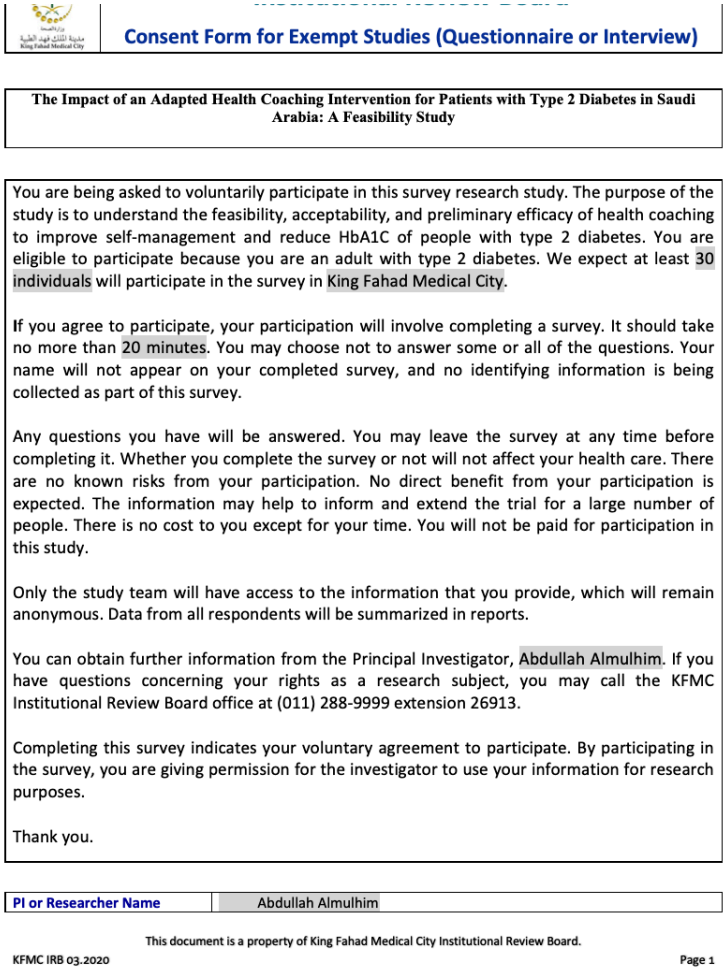
Appendix 0-12: Participants' mean differences in each group at baseline and endpoint for diabetes self-care activity questionnaire

					An independent two-sample t-test			
							95% Confidence Interval of the Difference	
	Group	N	Mean	Std. Deviation	Sig. (2-tailed)	Mean Difference		
On average, over the past month, how many days per week have you followed your eating plan? (At the baseline)	Intervention	14	2.36	2.098	.461	-.510	-1.909	.890
	Control	15	2.87	1.552				
On average, over the past month, how many days per week have you followed your eating plan? (At endpoint)	Intervention	14	4.86	1.610	.160	.790	-.333	1.914
	Control	15	4.07	1.335				
On how many of the last seven days did you eat five or more servings of fruits and vegetables? (At the baseline)	Intervention	14	2.29	1.590	.063	-1.181	-2.431	.069
	Control	15	3.47	1.685				
On how many of the last seven days did you eat five or more servings of fruits and vegetables? (At endpoint)	Intervention	14	3.93	1.385	.100	-.871	-1.923	.180
	Control	15	4.80	1.373				
On how many of the last seven days did you eat high fat foods such as red meat or full-fat dairy products? (At the baseline)	Intervention	14	2.50	1.912	.046	-1.167	-2.311	-.022
	Control	15	3.67	.976				
On how many of the last seven days did you eat high fat foods such as red meat or full-fat dairy products? (At endpoint)	Intervention	14	3.50	1.829	.323	-.633	-1.923	.656
	Control	15	4.13	1.552				
On how many of the last seven days did you space carbohydrates evenly through the day? (At the baseline)	Intervention	14	1.71	1.729	.236	-.686	-1.845	.474
	Control	15	2.40	1.298				
On how many of the last seven days did you space carbohydrates evenly	Intervention	14	4.00	1.240	.258	-.533	-1.481	.415

through the day? (At endpoint)	Control	15	4.53	1.246				
On how many of the last seven days have you followed a healthful eating plan? (At the baseline)	Intervention	14	1.64	1.447	.011	-1.490	-2.617	-.364
	Control	15	3.13	1.506				
On how many of the last seven days have you followed a healthful eating plan? (At endpoint)	Intervention	14	5.00	1.468	.452	.400	-.674	1.474
	Control	15	4.60	1.352				
On how many of the last seven days did you participate in at least 30 minutes of physical activity? (At the baseline)	Intervention	14	3.57	2.243	.674	.305	-1.165	1.775
	Control	15	3.27	1.580				
On how many of the last seven days did you participate in at least 30 minutes of physical activity? (At endpoint)	Intervention	14	5.64	1.692	.162	.776	-.331	1.884
	Control	15	4.87	1.187				
On how many of the last seven days did you participate in a specific exercise session (such as such swimming, walking, biking) other than what you do around the house or as part of your work? (At the baseline)	Intervention	14	2.29	2.016	.775	-.181	-1.465	1.103
	Control	15	2.47	1.302				
On how many of the last seven days did you participate in a specific exercise session (such as such swimming, walking, biking) other than what you do around the house or as part of your work? (At endpoint)	Intervention	14	4.93	2.018	.145	.929	-.342	2.199
	Control	15	4.00	1.254				

Appendix 13: The study's ethical approval and participation consent form

Appendix 0-13: The study's ethical approval and participation consent form



Consent Form for Exempt Studies (Questionnaire or Interview)

The Impact of an Adapted Health Coaching Intervention for Patients with Type 2 Diabetes in Saudi Arabia: A Feasibility Study

You are being asked to voluntarily participate in this survey research study. The purpose of the study is to understand the feasibility, acceptability, and preliminary efficacy of health coaching to improve self-management and reduce HbA1C of people with type 2 diabetes. You are eligible to participate because you are an adult with type 2 diabetes. We expect at least 30 individuals will participate in the survey in King Fahad Medical City.

If you agree to participate, your participation will involve completing a survey. It should take no more than 20 minutes. You may choose not to answer some or all of the questions. Your name will not appear on your completed survey, and no identifying information is being collected as part of this survey.

Any questions you have will be answered. You may leave the survey at any time before completing it. Whether you complete the survey or not will not affect your health care. There are no known risks from your participation. No direct benefit from your participation is expected. The information may help to inform and extend the trial for a large number of people. There is no cost to you except for your time. You will not be paid for participation in this study.

Only the study team will have access to the information that you provide, which will remain anonymous. Data from all respondents will be summarized in reports.

You can obtain further information from the Principal Investigator, Abdullah Almulhim. If you have questions concerning your rights as a research subject, you may call the KFMC Institutional Review Board office at (011) 288-9999 extension 26913.

Completing this survey indicates your voluntary agreement to participate. By participating in the survey, you are giving permission for the investigator to use your information for research purposes.

Thank you.

PI or Researcher Name	Abdullah Almulhim

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KFMC IRB 03.2020 Page 1

Participation consent form: English Version

Signature & Stamp (if applicable)	Stamp
Address	Regent Court, 30 Regent St, Sheffield S1 4DA
Contact Number	0541333494

لجنة أخلاقيات المهنة

نموذج الموافقة على الدراسات المعفاة (استبيان أو مقابلة)

موضوع الدراسة:
دراسة جدوى تطبيق برنامج التدريب الصحي المكيّف على السياق السعودي مع مرضى السكري النوع الثاني لتعزيز الإدارة الذاتية والتحكم بالمرض

يُطلب منك المشاركة الطوعية في دراسة البحث هذا. وهدف هذه الدراسة هو دراسة جدوى تطبيق برنامج التدريب الصحي المكيّف على السياق السعودي مع مرضى السكري النوع الثاني لتعزيز الإدارة الذاتية والتحكم بالمرض . حيث أنك مؤهل للمشاركة بسبب انطباق شروط الإنضمام مصاب بمرض السكري النوع الثاني-.

بموافقتك على المشاركة، ستشمل مشاركتك إكمال استطلاع و جلسات التدريب بواقع ٦ جلسات على مدى ثلاثة أشهر ، بواقع جلستين في كل شهر .. ولك الحق بعدم الإجابة عن بعض الأسئلة. حيث أنه لن يتم الإفصاح عن اسمك في استطلاعك المكتمل، ولن تُجمع أي معلومات تعريفية كجزء من هذا الاستطلاع.

سيتم الإجابة على أي أسئلة لديك. ولن يؤثر هذا على رعايتك الصحية في حال إكمالك للاستطلاع أو لا. حيث لا يوجد أي مخاطر معروفة عند مشاركتك. إذ أن المعلومات قد تساعد على دراسة جدوى تطبيق برنامج التدريب الصحي المكيّف على السياق السعودي مع مرضى السكري النوع الثاني لتعزيز الإدارة الذاتية والتحكم بالمرض . ولن يُكلفك هذا إلا وقتك.

لن يطّلع على المعلومات التي قدمتها إلا الباحث الرئيسي (عبدالله الملحم)، حيث ستبقى جميع البيانات مجهولة الهوية. وستُلخّص البيانات في تقارير ويتم إتلافها بعد انتهى الدراسة.

يمكنك الحصول على مزيد من المعلومات من الباحث الرئيس عبدالله الملحم (٠٥٤١٣٣٣٤٩٤) او مع المشرفة على البحث البرفسوره البزابيث e.goyder@sheffield.ac.uk. وإن كان لديك أسئلة تتعلق بحقوقك كمشارك في البحث، يمكنك الاتصال بمكتب لجنة أخلاقيات المهنة في مدينة الملك فهد الطبية على الرقم ٩٩٩٩-٢٨٨(٠١١) تحويلة ٢٦٩١٣.

يشير إكمالك لهذا الاستطلاع على موافقتك الطوعية على المشاركة. من خلال المشاركة في الاستطلاع، فأنت تعطي الإذن للباحث باستخدام معلوماتك لأغراض بحثية.

شكراً لك

اسم الباحث الرئيس	عبدالله الملحم
التوقيع والختم (إن وُجد)	Stamp
العنوان	
رقم التواصل	٠٥٤١٣٣٣٤٩٤

Participation consent form: Arabic version

نموذج موافقة للمشاركة

اسم البحث: دراسة جدوى تطبيق برنامج التدريب الصحي المكيّف على السياق السعودي مع مرضى السكري النوع الثاني لتعزيز الإدارة الذاتية والتحكم بالمرض

.اقر انا الموقع ادناه انني قد اعطيت معلومات واضحة و مكتوبة حول هذا المشروع البحثي واعطيت الوقت الكافي للنظر فيما اذا كنت ارغب المشاركة او لا

وأنا افهم هذا هو مشروع بحث دكتوراة وتحت اشراف فريق بحثي وسيتم استخدام نتائج هذا المشروع البحثي عن طريق الباحث عبدالله الملحم .

أنا افهم واستعرض طبيعة المشروع الذي يتم شرحه بأرياحية .وأفهم ايضا ان هذه المشاركة تتضمن جلسات تدريبيه مسجله لأغراض بحثيه وتحليليه وأنا اعلم ان مشاركتي في هذا المشروع طواعية وأعلم ايضا ان لدي حق الانسحاب في اي وقت .اذا كان لدي اي تساؤل عن هذا المشروع بكوني مشارك فيه فأنه باستطاعتي التواصل مع الباحث الرئيسي علي الجوال ٠٥٤١٣٣٣٤٩٤ اوعن طريق الايميل للباحث aalmulhim2@sheffield.ac.ukاو البرفسوره المشرفه على البحث اليزابيث e.goyder@sheffield.ac.uk

+44 114 222 0783.

هذا البحث مدقق وموافق عليه من لجنة أخلاقيات البحث في مدينة الملك فهد الطبية وجامعة شيفيلد البريطانية.

اوافق على المشاركة في هذا المشروع حيث أكد لي ان هويتي لن يتم الافصاح عنها ولن يذكر عنها اي شي في الدراسة والنشر. وافهم ان هذا البحث يجرى في مدينة الملك فهد الطبية في مدينة الرياض .

اسم المشارك:..... التوقيع:..... التاريخ.....:

اقرار الباحث:انني وضحت للمشارك شفهيا وكتابياً الخطوات الموجودة في البحث وان المشارك قد فهم وأدرك ذالك .

اسم الباحث: عبدالله الملحم التوقيع:.....التاريخ .....:

معلومات للمشاركين في الدراسة

عنوان المشروع :دراسة جدوى تطبيق برنامج التدريب الصحي المكيّف على السياق السعودي مع مرضى السكري النوع الثاني لتعزيز الإدارة الذاتية والتحكم بالمرض

حول هذه الدراسة :

هذا مشروع بحث دكتوراة في الفلسفة في جامعة شيفيلد تحت اشراف البرفسور إليزابيث قويدر من جامعة شيفيلد في المملكة المتحدة وسيتم استخدام نتائج هذا البحث من قبل طالب الدكتوراة عبدالله الملحم و هذا المشروع ممول من حكومة المملكة العربية السعودية .

وصف مشروع الدراسة :

هذا المشروع الذي يهدف لدراسة تطبق نهج جديد لأول مرة في السعودية (التدريب الصحي). هذا المنهج عبارة عن تدريب مرضى السكري النوع الثاني من خلال عقد جلسات مع المدرب لتطوير مهارات معينة لتمكن المريض من القدرة على إدارة مرض السكري بطريقة فعالة والسيطرة طويلة الأمد على هذا المرض. مدة التدريب الصحي ستكون ثلاثة اشهر وبمجموع ٦ جلسات بمعدل جلستين في كل شهر.

الغرض من هذه الدراسة :

صممت هذه الدراسة لفهم واستكشاف جدوى تطبيق هذا النهج الحديث والجديد على السياق السعودي. من خلال جمع وتحليل البيانات، سوف تتيح هذه الدراسة المجال لتوسيع وتكرار التجربة على نطاق واسع من خلال التعديل والتأكيد على جوانب معينه.

ماذا يراد مني ان افعل :

انت مدعو للإنضمام للمشاركة في هذا المشروع ومن سيقوم بالعمل معك هي مدربة تقوم بعقد جلسات ومتابعة وتنمية مهارات فرديه وتعليمية. الجلسات التدريبية ستكون مسجلة لأغراض بحثيه وتحليلية ومتابعة من قبل المدربة. جميع البيانات المكتوبة والمسجلة ستكون فقط مع الباحث الأساسي (عبدالله الملحم) وسيتم اتلافها بعد الانتهاء من الدراسه مباشرة .

ماذا سأستفيد من المشاركة في هذه الدراسة :

قد تتمكن بعد المشاركة في تنميه مهارات معينه تساعدك في السيطرة والتحكم بمرض السكري. ايضآ قد لايكون هناك فائدة مباشرة من المشاركة ولكن مشاركتنا البيانات سوف تساعدنا على تطوير برامج اكثر فاعلية في المستقبل وتطوير مجال التدريب الصحي في المملكة.

هل ستكون هويتهي معروفة بمجرد مشاركتي في هذه الدراسة :

سوف يتم اعطائك رقم ولانحتاج اسمك في هذه المشاركة وبعد الانتهاء من البحث سوف يتم اتلاف جميع البيانات والمحتويات. خلال فترة البحث (٣ اشهر) سيتم حفظ هذه المعلومات في مركز للبيانات مركزي لا يستطيع الوصول للبيانات الا الباحث الأساسي فقط ولمدة مؤقتة ولن يتم الافصاح عن شيء من المعلومات التي قد تدل على شخصيتك حيث سيتم التعامل مع المعلومات بصرامة و سرية وخصوصية تامة ولن يتم نشر الهوية في اي من منشورات البحث .

كيف اوافق على المشاركة؟

تستطيع المشاركة بحرية وطواعية كاملة من دون اي ضغوطات وعدم موافقتك للمشاركة سيكون مقبولا.

كيف استطيع الحصول على معلومات إضافية عن هذه الدراسة؟

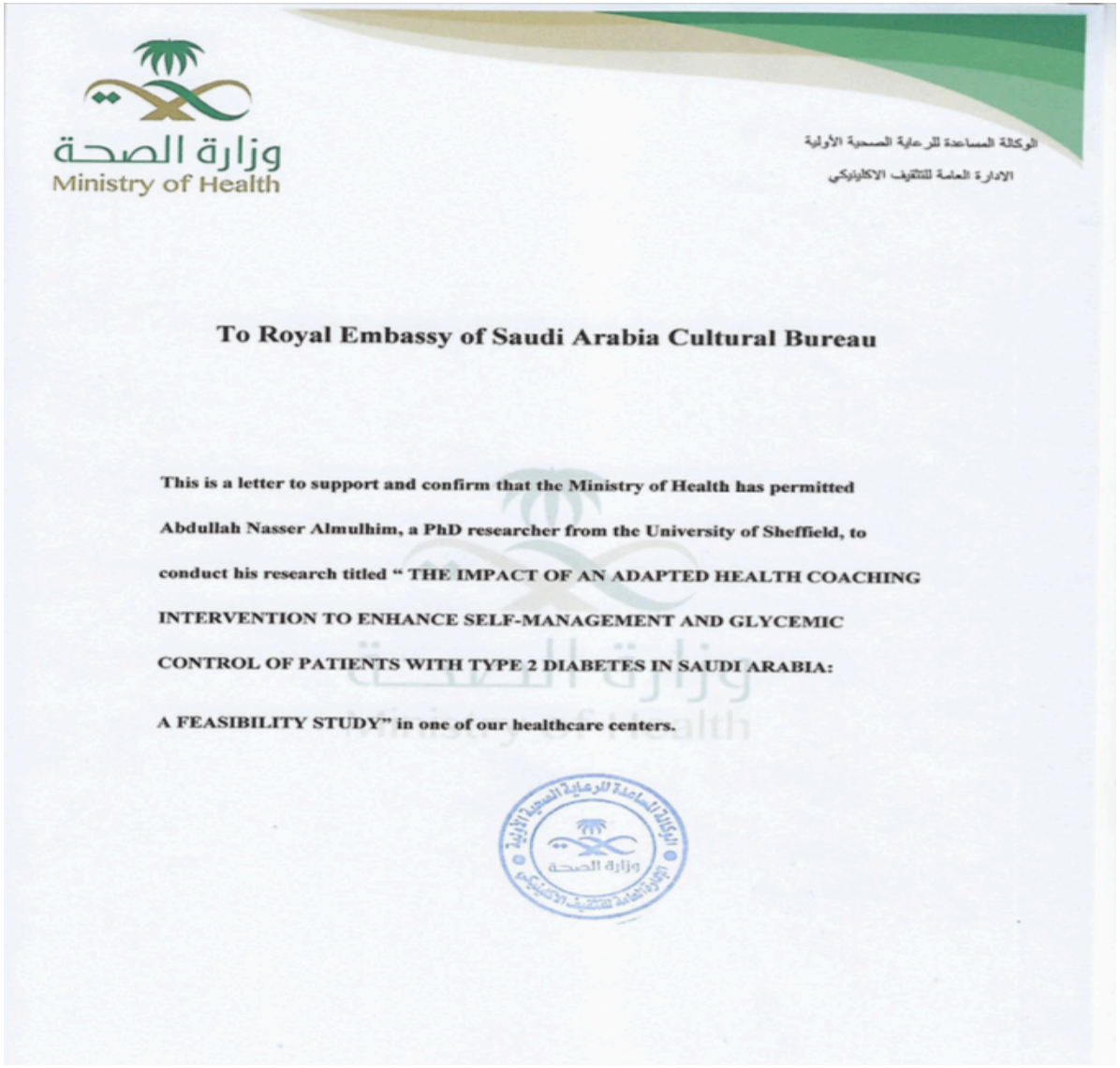
بأستطاعتك الاتصال على الباحث الأساسي/ عبدالله الملحم على ٠٥٤١٣٣٣٤٩٤ او البرفسور إليزابيث علىe.goyder@sheffield.ac.uk **:**

+44 114 222 0783

هذا البحث مدقق وموافق عليه من لجنة أخلاقيات البحث في مدينة الملك فهد الطبية وجامعة شيفيلد البريطانية.

شكرا جزيلا لوقتك الثمين الذي امضيته في قراة هذه المعلومات متمنيا قبولك للمشاركة في هذه الدراسة

Ministry of Health approval



وزارة الصحة
Ministry of Health

الوكالة المساعدة للرعاية الصحية الأولية
الإدارة العامة للتثقيف الاكلينيكي

To Royal Embassy of Saudi Arabia Cultural Bureau

This is a letter to support and confirm that the Ministry of Health has permitted Abdullah Nasser Almulhim, a PhD researcher from the University of Sheffield, to conduct his research titled " THE IMPACT OF AN ADAPTED HEALTH COACHING INTERVENTION TO ENHANCE SELF-MANAGEMENT AND GLYCEMIC CONTROL OF PATIENTS WITH TYPE 2 DIABETES IN SAUDI ARABIA: A FEASIBILITY STUDY" in one of our healthcare centers.

مدينة الملك فهد الطبية
King Fahad Medical City

IRB Registration Number with KACST, KSA: H-01-R-012
IRB Registration Number with OHRP/NIH, USA: IRB00010471
Approval Number Federal Wide Assurance NIH, USA: FWA00018774

August 22, 2021
IRB Log Number: 21-062E
Category of Approval: EXEMPT

Dear Dr. Abdullah Almulhim, Dr. Ali Alhaiti, Lama Alsubki and Manal AlKahtani,

We have received, reviewed and approved the amendment submitted on August 15, 2021 for the study titled '**The Impact of an Adapted Health Coaching Intervention for Patients with Type 2 Diabetes in Saudi Arabia: A Feasibility Study**' as per details below:

1. To remove: Ms. Lama Alsubki & Manal Alkahtani
2. To Add: Alaa A. Madani, Atheer Alhowaish and Munirah Alqaddan as Co-investigators.

Sincerely yours,

Institutional Review Board
Approved
Date: 22 AUG 2021

Dr. Hussam Sakkijha, FCCP, FACP, Diplomat, ABSIM
Chairman Institutional Review Board--IRB
Consultant, Critical Care, Pulmonary & Sleep Medicine
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E-mail: hsakkijha@kfmc.med.sa

KFMC research approval

Appendix 14: Email about systematic review from NHS Trust

Appendix 0-14: NHS Trust

Dear Mr. Almulhim,

I hope this email finds you well?

I have been looking on Prospero, and I have come across your protocol for the use of behavioural change techniques (BCTs) in health coaching-based interventions for type 2 diabetes patients: a systematic review.
I am interested about your findings as this is something that our NHS trust are running as service and it would be great to have this the findings from a research perspective.

Thank you for your time and I hope to hear from you soon.

Kind regards,
Katerina

Katerina Manginas
Health Improvement Practitioner/ Tobacco Dependence Specialist for Mental Health

Mobile: 07510 382455
Email: wlm.tr.HLS@nhs.net/ smokefree@westlondon.nhs.uk
Website: Diabetes health and wellness coaching (westlondon.nhs.uk)

Healthier Lifestyle Service, Ealing Community Partners
West London NHS Trust
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