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THESIS PORTFOLIO

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Thesis portfolio submitted in partial fulfilment of the requirements for a postgraduate Doctorate in Clinical Psychology at the University of Edinburgh.

Fabia Cientanni

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CONTENTS OF PORTFOLIO

Declaration of Own Work

Name: Fabia Cientanni

Title of Work: Understanding Uptake, Adherence, and Outcome in Computerised Cognitive Behavioural Therapy (cCBT): Evidence from Demographic, Clinical and Healthcare-Belief Perspectives

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For Pops.

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Glossary of Abbreviated Terms

Abbreviation	Term Represented by Abbreviation
APA	American Psychiatric Association
AteH	Attitudes towards eHealth
AXIS	Appraisal tool for Cross-Sectional Studies
BLR	Binary Logistic Regression
BtB	Beating the Blues
CASP	Critical Appraisal Skills Programme
CBT	Cognitive Behavioural Therapy
cCBT	Computerised Cognitive Behavioural Therapy
CORE-OM	Clinical Outcomes in Routine Evaluation – Outcome Measure
CRD	Centre for Review Dissemination
DLoC	Diabetes Locus of Control
DLoCS	Diabetes Locus of Control Scale
eHIQ	eHealth Impact Questionnaire
eHLoC	External Health Locus of Control
GP	General Practitioner
HLoC	Health Locus of Control
iHLoC	Internal Health Locus of Control
LoC	Locus of Control
MHLC	Multidimensional Health Locus of Control Scale
MLR	Multiple Linear Regression
MMAS-8	Morisky Medication Adherence Scale - 8
NHS	National Health Service
NICE	National Institute of Clinical Excellence
PICOS	Population Intervention Comparison Outcome Study
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses
SDSCA	Summary of Diabetes Self-Care Activities measure
S-DI	Self-Directed Intervention
SIM	Structural Equation Modelling
SIMD	Scottish Index of Multiple Deprivation
SIGN	Scottish Intercollegiate Guidelines Network

SLT	Social Learning Theory
UK	United Kingdom
WHO	World Health Organisation

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Thesis Abstract

Background: Health Locus of Control (HLoC), and health beliefs in general, have been found to play a role in the way in which people manage their healthcare needs. Increasingly, patients are being encouraged to self-manage a variety of health conditions, including chronic physical health conditions, such as diabetes, and mental health conditions, such as depression and anxiety. However, evidence regarding which factors might be related to response to self-management is limited. HLoC may help to explain why some take well to the self-management of health conditions, or respond to recommended remote therapies, whereas others struggle to implement advised changes. Similarly, attitudes towards eHealth (AteH) may play a role in engagement with specific remote therapies.

Aims & Objectives: The current thesis project aims to consolidate the existing research into the relationship between HLoC and diabetes self-management by conducting a systematic review of the literature (chapter 1), before exploring the concept of HLoC and AteH as potential predictors of response to computerised Cognitive Behavioural Therapy (cCBT), as defined by uptake (starting treatment), adherence (extent to which treatment is completed), and clinical outcome (magnitude of symptom reductions) in chapter 2.

Methodology: In chapter 1, a systematic review of the literature was conducted across three electronic databases (PsychINFO, Ovid MEDLINE, and Embase) to examine and critically appraise the literature regarding the relationship between HLoC and adherence to diabetes self-management**.** Studies included research investigating diabetes self-management in relation to HLoC. In chapter 2, a longitudinal study with three major time-points was conducted across *N*=2130 patients accessing cCBT services in Scotland to individually explore predictors of uptake, adherence and clinical outcomes.

Results: *N*=17 studies were identified and critically reviewed using the AXIS tool in chapter 1. Most were deemed to be of good methodological quality, with a small number of exceptions. The review revealed that the majority of studies found evidence to suggest that stronger internal HLoC beliefs were associated with better adherence to diabetes self-management regimens, however inconsistencies were found across certain HLoC domains, and the heterogeneity of predictor and outcome measures posed a challenge to inter-study comparisons. In chapter 2, neither of the healthcare belief-related factors were found to significantly predict uptake in cCBT

services, however both HLoC and AteH predicted higher adherence to cCBT, and various HLoC domains predicted magnitude of clinical changes across treatment. Other significant sociodemographic and clinical predictors of adherence and reductions were found and discussed.

Conclusions & Clinical Implications: Chapter 1 concluded that stronger internal HLoC beliefs are positively related with adherence to diabetes self-management regimens, which may improve health outcomes for those self-managing diabetes. However, further research is needed to apply causality to this model. Chapter 2 demonstrated interesting insights into the theoretical factors predicting response to cCBT, which may help inform clinicians in making referrals to the service.

Lay Thesis Summary

The NHS is developing new and innovative ways to provide psychological therapies such as cognitive behavioural therapy (CBT). CBT provides a way of understanding how peoples' thoughts and behaviours can be interlinked and can contribute to the way we are feeling. For example, if we engage in certain behaviours (such as excluding ourselves socially), this may increase the likelihood of experiencing negative thoughts and feeling alone, resulting in low mood. To improve mood, CBT encourages people to start breaking the harmful patterns associated with our thinking and behaviours. For a number of years, CBT has been delivered in one-to-one clinical settings, most commonly to people experiencing mild to moderate depression, but also other mental health difficulties. This involves meeting with a clinician and discussing the relationship between thoughts, behaviours, and mood, and completing relevant exercises to help improve mental health. However, recently programmes have been developed to allow CBT to be delivered in peoples' own homes through the use of the internet. This is called computerised CBT (cCBT). Since last year, cCBT has been made available to anyone eligible (those suffering from mild to moderate depression) in Scotland. For some people, this means not having to travel lengthy distances to attend clinical appointments, rather completing the treatment in the comfort of their own home. However, not everyone chooses to start cCBT after being referred by their clinician. This project aims to explore what factors might drive people to start and engage with cCBT, and what factors might predict improvements in how people are feeling having completed cCBT.

From a psychological perspective, one potentially important factor in determining whether people engage with cCBT is the extent to which people feel a sense of control over their health outcomes. This refers to the theory of Health Locus of Control (HLoC). The theory states that some people hold the belief that they are in control of their health outcomes, i.e. they have the power to improve their own health. This is called 'internal HLoC'. Others hold the belief that external entities are in control of their health, i.e. they might believe that luck or fate plays a role in whether their health improves. This is called 'external HLoC'. Given that cCBT relies on the individual making a considered effort to complete the therapy alone, we might predict that those with a more internal HLoC would be more likely to engage. Other factors may also be important, such as how people view using the internet to improve their health. We do not yet know enough about engagement and clinical gains in those referred to receive cCBT, however

it is hoped that this project will help to build an understanding of these factors so that we can improve the service we are providing to those experiencing mental health difficulties.

SYSTEMATIC REVIEW

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The Impact of Health Locus of Control (HLoC) on Diabetes Self-Management: A Systematic Review

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This systematic review is written in accordance with guidelines for publication in the *British Journal of Health Psychology* and in accordance with the PRISMA statement; please see Appendix I for author guidelines

Chapter 1. The Impact of Health Locus of Control (HLoC) on Diabetes Self-Management: A Systematic Review

The Impact of Health Locus of Control (HLoC) on Diabetes Self-Management: A Systematic Review

Abstract

Background: Diabetes is a condition which often relies heavily on self-management. The theory of Health Locus of Control (HLoC) stipulates that the degree to which one feels a sense of control over their health outcome is variable. HLoC may therefore help to explain why some take well to the self-management of diabetes, whereas others struggle to implement changes. ***Objectives:*** This review seeks to explore and evaluate literature examining the extent to which HLoC can explain adherence to diabetes self-management regimens. ***Data Sources:*** Three electronic databases were searched for relevant studies; PsychINFO, Ovid MEDLINE, and Embase. ***Hypothesis:*** It is predicted that the more control one believes to have over one's health (internalised HLoC), the more likely one is to adhere to diabetes self-management. ***Study Eligibility Criteria****:* Eligible studies included research which investigated HLoC as a potentially important factor in contributing to the adherence of diabetes self-management. ***Participants & Intervention:*** Those diagnosed with type I or II diabetes who have been prescribed a self-management regimen. ***Study Appraisal & Synthesis Methods:*** Studies were evaluated using an adapted version of the AXIS tool following a systematic search of the literature. ***Results:*** The majority of studies found evidence of internalised HLoC being positively related to adherence to various types of diabetes self-management regimens, including diet, exercise / weight management, dental care, foot care, and blood glucose monitoring. ***Limitations:*** The literature consisted primarily of cross-sectional designed studies; thus, causality cannot be inferred. In addition, the heterogeneity of outcome measures of diabetes self-management adherence makes the results across studies difficult to generalise. ***Conclusions and Implications of Key Findings:*** It is possible that fostering internalised HLoC might increase adherence to diabetes self-management, which may improve health outcomes for those with diabetes, however further research is needed to apply causality to this model.

Systematic Review Registration No/.: CRD42019159603

Key Words: Health Locus of Control (HLoC); Diabetes; Self-management; Adherence

1. Introduction

1.1 Diabetes Mellitus

Diabetes mellitus (commonly known as diabetes) is a chronic disease which effects the way in which the body metabolises sugars. It is a major public health concern with a prevalence which continues to rise globally. The number of people aged between 20-79 years diagnosed with type I or II reached 463 million worldwide in 2019 (Saeedi *et al*., 2019). In the UK, over 2.5 million people were estimated to be living with diabetes in 2010, and this figure is predicted to rise to over 4 million by 2025 (Diabetes UK, 2010). This has significant implications for the level of care and services that the National Health Service (NHS) must provide.

1.2 Diabetes Self-Management

Historically, chronic health problems such as diabetes have been treated using a medical model, whereby healthcare professionals took the responsibility for diagnosing, treating and following-up health outcomes for patients. More recently, there has been a shift towards patient-empowerment in managing chronic health conditions, encouraging patients to take a more active role in their treatment plan, which is broadly described as "self-management". It is estimated that 95% of diabetes treatment involves prescribed regimens of self-management (Diabetes UK, 2010). Self-management has been defined as everyday activities or actions individuals are advised to undertake in order to control or reduce the negative impact of their health condition, to prevent further illness, and to improve general health and wellbeing (Adu *et al*., 2019). For diabetes, this might consist of a considerable lifestyle change, including following recommended behavioural interventions such as healthy eating, medication regime adherence, increasing physical activity, reducing risks and monitoring blood glucose levels, all of which are necessary to successfully manage the disease (Tomky *et al*., 2008).

However, the extent to which patients adhere to diabetes self-management plans varies. Research consistently demonstrates that adherence to self-management regimes is sub-optimal for both patients with type I and type II diabetes (Peyrot *et al*., 2005). Poor adherence to self-management places patients at risk of serious health complications. However, consistent engagement with diabetes self-management programmes has been found to correlate with improved health outcomes, including fewer diabetes-related health complications (Chen, Sloan & Yashkin, 2015), better blood glucose control (Norris *et al*., 2005), and overall improved quality of life.

1.3 Potential Barriers and Enablers in Diabetes Self-Management

With regards to factors which might influence effective diabetes self-management, a number of aspects have been considered within the literature. Adu *et al.* (2019) conducted a multi-national study spanning across Europe, Australia, Asia and America to investigate potential barriers to and enablers of diabetes self-management, focusing on the skills required to achieve optimal diabetes control. The study used an online survey and telephone interviews to contact people with type I and type II diabetes to explore the skills of self-efficacy, as well as perceived enablers of and barriers to effective diabetes self-management. The survey revealed that a lack of certain self-management skills, including the ability to recognise and manage the impact of stress on diabetes, plan exercise to avoid hypoglycaemia and correctly interpret blood glucose patterns, were related to poor diabetes control. The interviews identified that a want to prevent diabetes complications and the use of technological devices such as mobile apps were common enablers of effective diabetes self-management, whereas frustration surrounding the dynamic and chronic nature of diabetes, financial constraints, unrealistic expectations, and factors relating to participant's home and work environments were barriers. Whilst the study was conducted multi-nationally, the response rate to the online survey was limited with only 217 responses, therefore raises questions regarding the generalisability of the findings. Regardless, from Adu *et al*.'s study it is evident that a number of psychological factors may be at play in the self-management of diabetes.

1.4 Measuring Diabetes Self-Management

Given that diabetes treatment relies heavily on self-management, valid and reliable measures of this construct are needed (Toobert, Hampson & Glasgow, 2000). Diabetes self-management often requires a range of different activities, including blood glucose monitoring, following the recommended diet, and footcare regimen, and it has been found that these independent activities do not highly correlate (Bennet Johnson, 1992; Orme & Binik, 1989; Glasgow, McCaul & Scafer, 1987). As such, diabetes self-management can be considered as multidimensional, therefore it has been suggested that each aspect of self-management should be assessed individually (Johnson, 1992; Toobert, Hampson & Glasgow, 2000). Depending on the specific aspects of self-management which are intended to be investigated, a variety of tools are available.

Biological assessment diabetes self-management involves measuring haemoglobin glycaemic control (HbA1c). Measuring HbA1c provides an indication of blood glucose regulation over an

approximate 8-week period (Blanc *et al*.,1981). However, if the aim of the research is to monitor adherence to diabetes self-management regimens, using HbA1c as the sole measure is flawed, as numerous factors which contributing to HbA1c control are not accounted for (Przyblski, 2010).

The General Adherence Scale—Specific Measure (GAS-SM; Hays *et al*., 1994) was designed to assess adherence to prescribed medical treatments for chronic conditions such as diabetes, hypertension, and heart disease. The GAS-SM involves asking participants to indicate, from a list of 13 specific treatment options, which options have been recommended as part of their treatment plan. Participants are then asked to rate the extent to which they are adhering to each recommendation. This creates an individualised measure of adherence based on the personal treatment plan of each participant. Despite reported wide-scale use of measures based on the GAS-SM (Makarem, Smith, Mudambi & Hunt, 2014), no study to date has validated the measure. Similarly, the 8-item Morisky Medication Adherence Scale–8 (MMAS-8; Morisky *et al*., 2008) can be used to measure medication regimen adherence, based on the recommended time medication is taken, dosage, and frequency. Items 1-7 assess common potential reasons for non-adherence, including, forgetfulness, inconvenience, and feeling as though medication is making things worse. Item 8 adopts a 5-point Likert scale to assess frequency of forgetting to take medication, ranging from 'never/rarely' to 'all the time'.

Perhaps the most specific measure of diabetes self-management is the Summary of Diabetes Self-Care Activities Scale (SDSCA; Toobert, Hampson, & Glasgow, 2000). The SDSCA is a self-report questionnaire which assesses the following aspects of the diabetes self-management: general diet, specific diet, exercise, blood-glucose testing, foot care, and smoking. The validity and reliability of the SDSCA was assessed by collating data from 7 studies which used the tool (Toobert, Hampson, & Glasgow, 2000). Toobert, Hampson and Glasgow found that studies which used the SDSCA typically did so in populations of older patients with chronic type II diabetes. Mean correlations within scales were found to be high (.47), and mean test-retest correlations were moderate (.40). The study concluded that mean correlations between the SDSCA and comparable measures of diet and exercise indicated and supported the validity of the SDSCA subscales (.23).

In summary, there are a range of different measures which can be adopted to measure adherence to diabetes self-management recommendations, therefore the ability to generalise studies

examining this construct may be complicated by the heterogeneity of the measures used to investigate this factor.

1.5 Health Locus of Control

Health locus of Control (HLoC) is a psychological construct which considers the perceived source of reinforcement for health-related behaviours, based on the principles of social learning theory (SLT; Rotter, 1954). HLoC theory posits that reinforcement for health-related behaviours can be derived from two main sources of HLoC on opposite ends of a spectrum, from internally derived to externally derived. Internalised HLoC (iHLoC) describes the belief that one has personal control over one's health outcomes, i.e. the source reinforcement is internal. For example, those with iHLoC might believe that the behaviours they engage in, such as exercising consistently and eating well, will have a direct impact on the state of their health. Those with greater iHLoC have been found to engage more in positive health-related behaviours, such as increased physical exercise (Mercer *et al*., 2018), weight loss (Neymotin & Nemzer, 2014), and good dental care (Kneckt, Syrjälä, & Knuuttila, 1999). Externalised HLoC (eHLoC) on the other hand describes the belief that one has little control over what happens to one's health, i.e. the source of reinforcement is external. For example, those with eHLoC might believe that others around them, such as their doctor, holds more control over their health than they themselves.

1.6 Measuring Health Locus of Control

Wallston and colleagues developed a questionnaire to measure and categorise HLoC beliefs, forming the Multidimensional Health Locus of Control Scale (MHLC; Wallston *et al*., 1994). The MHLC is a item measure which assesses various dimensions of HLoC, including 'internal' HLoC (the belief that an individual's own actions determines their heath outcomes), 'doctors' HLoC (the belief that the doctors determine personal health outcomes), 'others' HLoC (the belief that other people, such as family members, determine personal health outcomes), and finally 'chance' HLoC (the belief that personal health outcomes are determined by chance, or luck). The MHLC form C was designed to measure the above listed dimensions of HLoC in relation to specific health conditions (Wallston, Stein, & Smith, 1994; Luszcynska & Schwarzer, 2005). A scale validation study by Wallston, Stein and Smith (1994) found form C to have a clean factor structure with factor loadings of >.7, good internal consistency (Cronbach's alpha >.70), and concurrent validity with significant correlations between .30 and .68 between subscales. However, it should be noted that the scale was validated within a

physical health population (those experiencing arthritis and other chronic pain), rather than those with diabetes.

Based on the MHLC, Ferraro, Price, Desmond and Roberts (1987) developed the Diabetes Locus of Control Scale (DLoCS) to investigate HLoC within a diabetes population in order to assess this construct against diabetes self-management. The DLoCS consists of 18 items and has been validated within a diabetes population (Ferraro, Price, Desmond, & Roberts, 1987). When compared with the MHLC, each DLoCS subscale demonstrated higher reliability coefficients. Test-retest reliabilities as determined by Cronbach alpha values ranged between .72 and .77 across subscales, compared to the range of between .66 and .74 demonstrated by the MHLC (Ferraro, Price, Desmond, & Roberts, 1987).

1.7 Overview of Review Articles

No review to date has explored the relevance of HLoC in diabetes self-management, however, some related reviews are briefly outlined as follows. Strudler Wallston and Wallston (1978) conducted an early narrative review of the literature to investigate the impact of HLoC in health care. The review concluded that those with stronger iHLoC tended to engage more in positive health behaviours across a range of health-related conditions and activities. This is the first review to summarise the evidence of the relationship between HLoC and health-related behaviours, however, is now considerably outdated given it was conducted in 1978, and it is flawed by reviewing a mix of both directed intervention studies and more generalised health-behaviour studies. Two further significant reviews have been conducted more recently to investigate the relationship between HLoC and health-related behaviours. Cheng, Cheung and Lo (2016) conducted a meta-analysis to investigate the impact of three domains of HLoC (internality, powerful others, and chance) on both specific health behaviours and global health appraisal. Interestingly, Cheng, Cheung and Lo found that the effect of HLoC on specific health-related behaviours was relatively weak across the N=144 studies analysed, with Pearson's R values ranging between (-.07 and .10). Náfrádi, Nakamoto and Schulz (2017) conducted the most recent related review to the current study, investigating the influence of patient empowerment in the relationship between self-efficacy, HLoC and medication adherence. They reviewed N=154 and found that stronger iHLoC beliefs were consistently related to improved adherence to medication regimens, whereas stronger eHLoC beliefs tended to have a negative influence on, or inconsistent links with, medication adherence.

A summary of related existing reviews can be found in table 1.

Table 1. *Relevant Existing Reviews on Health Locus of Control and Health Behaviour*

Author(s), Year, Title & Origin	Number of Studies	Main Question / Objectives	Methods	Publication Date Period	Main Findings	Conclusions
Strudler Wallston & Wallston (1978) Locus of control & health: A review of the literature USA	N/A	What is the role of health behaviour and sick role behaviour in engagement with health-positive activities e.g. non-smoking, healthy eating, exercise etc.?	Narrative review	1963-1977	Those with internal HLoC tended to engage more in positive health behaviours across a range of health-related conditions and activities. This is the first review to provide initial evidence of the relationship between HLoC and health-related behaviours	Having an internal HLoC is related to healthier living in general. The implications of these findings for health educators were discussed, noting the value of training 'internality' (encouraging self-efficacy)
Cheng, Cheung & Lo (2016) Relationships of HLoC with specific health behaviours and global appraisal: a meta-analysis and effects of moderators China	144	Aimed to investigate the impact of three domains of HLoC (internality, powerful others, and chance) on both specific health behaviours and global health appraisal	Three-level mixed-effects meta-analysis Explored potential moderators of the relationship including age, gender, individualism and power distance	Unknown	Correlations between HLoC and specific health behaviours were generally weak (R range from -.07 to .10), however a moderation effects were found between power HLoC and exercise (all four demographic moderators) and all 3 HLoC dimensions and diet (gender and individualism)	Highlights the importance of cultural considerations (individualism vs collectivism – cultural self-construal theory, Markus & Kitayama 1999) and supports Levenson's (1981) tripartite theory (external control)

Author(s), Year, Title & Origin	Number of Studies	Main Question	Methods	Publication Date Period	Main Findings	Conclusions
Náfrádi, Nakamoto & Schulz (2017) Is patient empowerment the key to promote adherence? A systematic review of the relationship between self-efficacy, HLoC and medication adherence Switzerland	154	Aimed to explore the relationship between patient empowerment and medication adherence	Systematic review in accordance with the PRISMA statement. Used a 13-item checklist by Wallace *et al.* (2006) to assess the quality of the reviewed studies	1967-2017	High levels of self-efficacy and iHLoC were consistently found to promote medication adherence. External HLoC dimensions were mainly found to have negative or ambiguous links to adherence, except doctor HLoC which had a positive association with medication adherence	Discusses the possibility of a 'joint empowerment' approach to fostering medication adherence, whereby both the doctor and the patient themselves hold some level of perceived control over the health outcome

1.8 Key Methodological Issues

The current review aims to address the following key methodological issues within the literature. The issues surrounding reliability and validity of measures adopted by studies to gauge adherence to diabetes self-management regimens will be critiqued, and the generalisability of findings will be assessed, with sociocultural issues considered.

1.9 Importance of examining HLoC and Diabetes Self-Management

HLoC has been linked with various types of health behaviour and condition management, however, no previous reviews have synthesised the evidence relating to HLoC and diabetes self-management. As stated previously, diabetes as a life-limiting condition requires significant self-management, and there is evidence to suggest that HLoC may be related to the likelihood of adhering to such self-management regimens.

1.10 Rational and Aim for Review

The aim of the current review is to develop a better understanding of the theoretical underpinnings of adherence to diabetes self-management regimens, as this may guide current clinical practice by informing both patient and clinician on the likelihood of adhering to the recommended treatment plan based on existing health-related beliefs. Based on existing reviews (Strudler Wallston & Wallston, 1978; Cheng, Cheung & Lo, 2016; Náfrádi, Nakamoto & Schulz, 2017), it is hypothesised that the current review will find HLoC to be an important factor in determining adherence to self-directed health interventions. However, the argument that HLoC influences adherence will be placed under scrutiny by the current review. The null hypothesis is that HLoC has no effect on diabetes self-management. A key distinction between the current systematic review and previous reviews related to HLoC and health behaviours is that the current review seeks to investigate the relationship between HLoC beliefs and diabetes self-directed, or self-managed, interventions as prescribed by health professionals.

To explore the above research question in a coherent manner, the current review will adopt the following structure. First, the methodology adopted by the current study to review the existing relevant literature will be clearly outlined under the methods section. The review will then summarise the results of the search and critically appraise and compare the relevant studies under the results section, before finally evaluating and drawing conclusions from the results under the discussion section.

2. Methods

2.1 Review Protocol

The study protocol and methodology reporting were informed by the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRIMSA) recommendations (Moher *et al.,* 2009) and the Centre for Reviews and Dissemination (CRD; 2009). The current systematic review was registered on PROSPERO (registration number: CRD42019159603): https://www.crd.york.ac.uk/PROSPERO/display_record.php?RecordID=159603

A copy of the PROSPERO registration form can be found in appendix II.

2.2 Search Strategy

At first, an initial scoping search was conducted via the google scholar search engine to check the feasibility of the review idea. The following term was entered: "health locus of control and diabetes self-management" into google scholar search engine. Secondly, a search of the Cochrane Library database and PROSPERO database was conducted to check for any existing relevant systematic reviews and if any relevant systematic reviews are in progress and due to be published in the near future.

The search strategy was informed by consultation from expert University and NHS librarians. To identify research relevant to investigating the impact of HLoC on diabetes self-management, EMBASE, Ovid MEDLINE and PsycINFO were searched.

2.3 Search Terms

The review question was broken down into the core constituent parts following a "population, intervention, comparison, outcome, study" (PICOS; Richardson *et al*., 1995) structure in order to identify key search terms, as displayed in table 2.

Table 2. *PICOS Search Terminology used to Investigate the Review Question*

Diabetes	**Self-management**	**HLoC**	**Adherence**
diabe*	self*manage*	(health) locus of control	adher*
HbA1c	self*directed	(H)LoC	engage*
	intervention	(D)LoC	drop*out
	treatment		attrition
			compliance
			comply
			discontinuation

As noted, the asterisk included in the term "drop*out" allows for any spelling variations (drop-out / dropout) to be detected. Both the terms "adherence" and "engagement" were searched for, as these terms are used interchangeably within the literature, as are "drop*out" and "attrition", and "intervention" and "treatment". The search terms were constructed in this way in an attempt to conduct a wide and comprehensive search. Additional search terms were identified through the initial search process, and these were used to inform the final search terminology list displayed in table 2.

A preliminary search of the literature was conducted in June 2019 and a repeat of the initial search was completed in January 2020 as to ensure that no additional studies had been published in the interim. A table showing the search term combinations entered into Ovid and the corresponding records identified can be found in appendix IV.

2.4 Study Eligibility Criteria

For the purpose of the current review, "self-management" of diabetes is defined as any intervention which requires an aspect of lifestyle change to effectively manage diabetes e.g. a change of diet with regular monitoring of blood glucose levels, exercise, or medication regimen adherence. Based on Náfrádi, Nakamoto and Schulz's (2017) categorisation of adherence-measuring methodology, the following types of adherence types are defined; (a) objective measures e.g. counting number of sessions attended as a proxy of adherence or measuring HbA1c, (b) subjective measures e.g. self-reported questionnaire items regarding adherence, and (c) mixed measures e.g. both objective and subjective measures combined to inform an understanding of adherence. All measures of HLoC or DLoC were considered by the current study in order to avoid measurement bias. A summary of the study inclusion and exclusion as structured by PICOS can be found in table 3.

Table 3. *PICOS Study Inclusion and Exclusion Criteria*

	Criteria	
	Inclusion	**Exclusion**
Participants	• Participants with type-I or type-II diabetes	• Sample with participants <16 years of age • Prison samples • In-patient samples
Interventions	• Self-management interventions	• Interventions which measure only medication adherence
Comparisons	• None applicable	• None applicable
Outcomes	• Studies which investigate adherence to a self-management intervention as an outcome measure	• None applicable
Studies (design)	• Empirical studies investigating the relationship between HLoC and diabetes self-management	• Qualitative studies • Studies which fail to include a measure of HLoC or DLoC

2.5 Additional Searches

Through the search process, key words were screened to identify any additional search terms. Having identified a selection of eligible studies for review, a search within the reference section of each study was conducted. In addition, key authors field of HLoC were then contacted to enquire whether they were aware of any additional studies appropriate to include in the current review which may have been missed from the initial search.

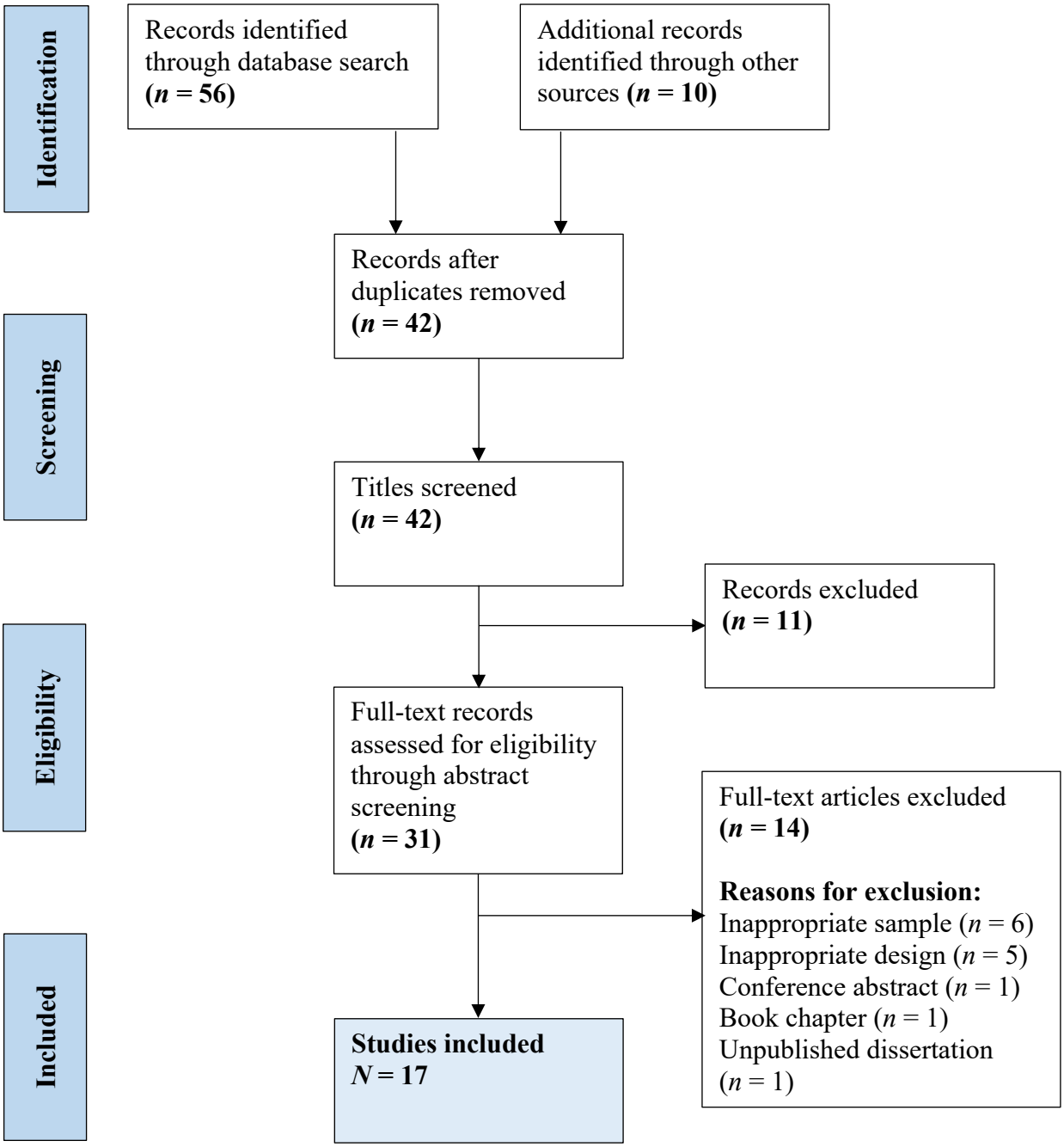
2.7 Data Extraction

Records identified through the search were screened against the inclusion and exclusion criteria. Records were at first screened by title and abstract to identify and exclude irrelevant studies. Full-text articles were then screened for inclusion against the criteria of adopting an appropriate design to investigate the relationship between HLoC and adherence, an outcome measure which encapsulates adherence to a self-managed intervention (diet, exercise, medication, self-reported adherence or HbA1c control), and an appropriate diabetic population (type-I, type-II or a mixed sample).

3. Results

The search strategy identified *N*=56 records from the electronic databases. An additional *N*=10 records were identified through manual searching the reference sections of relevant studies and existing reviews. The initial search results and subsequent staged screening process to produce the final number of included studies are detailed in figure 1, along with the reasons for study exclusions. A reference list of the excluded studies is provided in appendix IV.

Figure 1. *A PRISMA Diagram to Illustrate the Systematic Screening Process*



3.1 Summary of the Included Studies

The systematic search identified a total of *N*=17 studies eligible for inclusion in the current review (Albargawi, Snethen, Al Gannass, & Kelber, 2017; Alogna, 1980; Amsberg, *et al*., 2009; Habib, & Durrani, 2016; Kang, & Hur, 2019; Kacerovsky-Bielesz, *et al*., 2009; Klinovszky, Márton Kiss, Papp-Zipernovszky, Lengyel, & Buzás, 2019; Kneckt, Syrjälä, & Knuuttila, 1999; Makarem, Smith, Mudambi, & Hunt, 2014; Morowatisharifabad, Mahmoodabad, Baghianimoghadam, & Tonekaboni, 2010; O'Hea, *et al.*, 2005; Quiñones, Ugarte, Chávez, & Mañalich, 2018; Schlenk & Hart, 1984; Stenström, Wikby, Andersson, & Rydén, 1998; Tillotson & Smith, 1996; Wooldridge, Wallston, Graber, Brown, & Davidson, 1992; Zahednezhad, Poursharifi, & Babapour, 2011).

The majority of studies employed a cross-sectional design to investigate the relationship between HLoC and diabetes self-management. One of the included studies (Quiñones, Ugarte, Chávez, & Mañalich, 2018) was only available in Spanish, however translating software was used to produce an English version.

Studies were conducted across North America, South America, Asia and Europe, within the following countries: Austria, Hungary, Sweden, Finland, Saudi Arabia, South Korea, Iran, India, Chile, and the United States of America. The total number of participants across all studies was N = 2634, N^{Median} = 135, with one study which did not report the number of participants studied.

Data concerning participant characteristics (*N*, gender, mean age, and diabetic illness type), study design, aims, outcome measure(s), analyses, and results were extracted and tabulated in table 4.

Table 4. *Characteristics of Included Studies*

Author(s), Year & Origin	*N* (% female), ^{Mean}Age ± SD	Population, Design & HLoC Measure	Aims & Objectives	Outcome Measure(s) & Analysis	Results
Albargawi *et al.* (2017) *Saudi Arabia*	*N* = 30 (40%) ^{Mean}Age not reported	Type-II diabetics Correlational design MHLC	To examine the relationship between health beliefs and adherence to a daily self-management regimen	Self-reported measures of health beliefs, patient demographics, and daily diabetes self-management regimen Hierarchical multiple regression analysis	Participants with high eHLoC and high self-efficacy adhered well to their medication regimen (*P* = .035), whereas those with high iHLoC adhered well to their diabetic foot care regimen (*P* = .038)
Alogna (1980) *USA*	*N* = 50 (80%) No age data reported	Comparison of compliant and noncompliant, obese, non-insulin-dependent diabetics	To investigate the relationship between HLoC and compliance and non-compliance to diabetes self-management based on prescribed weight-loss	Outcome based on comparison between compliant and non-compliant groups (weight in lbs) *T*-tests	Compliant patients exhibited higher iHLoC than non-compliant patients No empirical data reported
Amsberg *et al.* (2009) *Sweden*	*N* = 94 Gender information not reported ^{Mean}Age not reported	Poorly controlled type-II diabetics randomised to a behavioural medicine condition or a control condition DLoCS	To investigate predictors of HbA1c control	HbA1c Backward stepwise regression models	No predictors or associations were found
Habib & Durrani (2016) *India*	*N* not reported (49.5%) ^{Mean}Age not reported, age range 30-60 years	Type-II diabetics Predictor model MHLC	To investigate the relationship between HLoC and diabetes self-management regimen adherence	Self-reported SDSCA Hierarchical regression	iHLoC was found to be a strong predictor of better compliance (/\R2 = .175, *F* = 7.014, *p* < .001)

Author(s), Year & Origin	***N* (% female), ^{Mean}Age ± SD**	**Population, Design & HLoC Measure**	**Aims & Objectives**	**Outcome Measure(s) & Analysis**	**Results**
Kacerovsky-Bielesz *et al.* (2009) *Austria*	*N* = 257 (50.9%) ^{Mean}Age = 64 ± 9	Type-II diabetics Correlational design DLoCS	To investigate sex-related differences in diabetes glucometabolic diabetes self-management	Single-item self-report five-point scale on compliance ("I follow the therapy recommendations") and HbA1c Multiple linear regression	Major predictors of poor HbA1c control included depressive coping, lower sexual desire, quality of life and higher iHLoC, but high external doctor-related HLoC in women was found to be related to hyperglycaemia
Kang & Hur (2019) *South Korea*	*N* = 175 (67.4%) ^{Mean}Age = 56.59 ± 11.15	Type-II diabetics Descriptive correlational and cross-sectional survey design DLoCS	To explore the relationship between diabetes medication adherence and diabetes knowledge, self-efficacy and DLoC	Medication adherence using the MMAS-8 Hierarchical multiple regression	No significant relationship was found between DLoC and medication adherence; self-efficacy was found to be the most influential predictor of medication adherence
Klinovszky *et al.* (2019) *Hungary*	*N* = 113 (66.4%) ^{Mean}Age = 60.56 ± 12.94	Type-II diabetics Cross-sectional design HLoC	To investigate the relationship between various types of adherence and psycho-demographic variables including HLoC and self-efficacy	Diabetes adherence questionnaire Spearman's rank correlation & multivariate regression	Blood glucose monitoring adherence was significantly predicted by social–external HLoC, diabetes self-efficacy, and iHLoC, while dietary adherence was predicted by self-efficacy and duration of the illness. Understanding and following the diabetes treatment were significantly associated with dietary adherence and high levels of self-efficacy, while health literacy was mostly predicted by iHLoC

Author(s), Year & Origin	***N* (% female), ^{Mean}Age ± SD**	**Population, Design & HLoC Measure**	**Aims & Objectives**	**Outcome Measure(s) & Analysis**	**Results**
Kneckt *et al.* (1999) *Finland*	*N* = 149 (41.6%) ^{Mean}Age = 34 ± 12	Insulin-dependent diabetics with teeth of their own Cross-sectional design DLoCS	To evaluate the relationship between dental and DLoC and the ability of LoC beliefs to predict oral health behaviour, dental status, diabetes compliance and HbA1c levels	HbA1c and self-reported diabetes self-management adherence Spearman's rank correlation & multivariate regression	DLoC correlated weakly with diabetes adherence (r = 0.17, p = 0.052), and did not correlate with the mean HbA1c level (r = 0.04, p = 0.641). No associations between DLoC and oral health behaviour were found
Makarem *et al.* (2014) *USA*	*N* = 222 (45%) No age data reported	Type-II diabetics Cross-sectional survey design Adapted HLoC	To formulate a model for understanding adherence to diabetes self-management by exploring concepts of hope and HLoC	Self-reported diabetes self-management adherence using the GAS-SM *T*-tests, mediation, SEM	Effects of iHLoC (t = 2.089, p <.05), chance-HLoC (t = 3.253, p <.05) and doctor-HLoC (t =2.526, p <.05) were positively significant on adherence. Hope mediated the effects iHLoC and doctor-HLoC on adherence
Morowatisharifabad *et al.* (2010) *Iran*	*N* = 120 (60.8%) ^{Mean}Age = 53.28 ± 10	Type-I and type-II diabetics Cross-sectional design DLoC	To investigate the relationship between DLoC and adherence to diabetes self-management regimen	Self-reported SDSCA *T*-tests, one-way ANOVAs and Pearson r correlations	No significant correlations were found between adherence and DLoC subscales among men, but internal and powerful others DLoC were positively correlated with adherence among women (r = 0.451 and r = 0.251, respectively). When type-I diabetics were excluded, significant correlations were found between adherence and internal and chance DLoC (r = 0.295 and r = -0.228, respectively)

Author(s), Year & Origin	*N* (% female), ^{Mean}Age ± SD	Population, Design & HLoC Measure	Aims & Objectives	Outcome Measure(s) & Analysis	Results
O'Hea *et al.* (2005) *USA*	*N* = 109 (74%) ^{Mean}Age = 52 ± 11.16	Low-income type-II diabetics Two-way interaction model MHLC Form C	To examine the interactions between five dimensions of HLoC beliefs and their relationships with diabetes medical regimen adherence	HbA1c Multivariate regression analysis	Various interactions were related to poorer HbA1c control including high chance HLoC beliefs with low iHLoC, high God HLoC with low iHLoC, and high other people HLoC and high Chance HLoC
Quiñones *et al.* (2018) *Chile*	*N* = 192 (78%) ^{Mean}Age = 64.2 ± 10.4	Type-II diabetics MHLC Form C	To identify associations between psychological profile and adherence to diabetes regimen	HbA1c dichotomised into 'adherent' (HbA1c <7%) and 'non-adherent' (HbA1c ≥7%) *T*-tests	Diabetic complications (diabetic foot and renal damage) were significantly associated with high eHLoC
Schlenk & Hart (1984) *USA*	*N* = 30 (50%) ^{Mean}Age = 29 SD not reported	Insulin-dependent diabetics MHLC	To explore the relationship between compliance with diabetes self-management and HLoC, health value, and perceived social support	Self-report and direct observation of compliance Multiple regression	A significant relationship was found between compliance and social support ($P < 0.001$), powerful others HLoC ($P < 0.01$), and iHLoC ($P < 0.05$)
Stenström *et al.* (1998) *Sweden*	*N* = 312 (41.6%) ^{Mean}Age = 50.2 ± 16	Insulin-dependent diabetics Cross-sectional correlation DLoCS	To examine the relationship between DLoC and HbA1c	HbA1c ANCOVA & eta-square	Those with high iHLoC and low chance HLoC exhibited better HbA1c control than those with the opposite pattern

Author(s), Year & Origin	***N* (% female), ^{Mean}Age ± SD**	**Population, Design & HLoC Measure**	**Aims & Objectives**	**Outcome Measure(s) & Analysis**	**Results**
Tillotson & Smith (1996) *USA*	*N* = 465 (72.7%) ^{Mean}Age = 59.62 ± 12.24	Non-insulin-dependent diabetics Cross-sectional predictor model DLoCS	To assess the ability of DLoC and social support to predict adherence to a weight-control regimen	SDSCA Pearson's R correlations, ANOVA, hierarchical multiple regression	Both iDLoC and social support were significant predictors of adherence (β = -.12, $p < .05$; β = .09, $p < .05$) respectively
Wooldridge *et al.* (1992) *USA*	*N* = 189 (50%) ^{Mean}Age = 45.6 SD not reported	Endocrinology patients (66% type-II diabetics) Pre- post-measures design DLoCS & MHLC Form C	To determine whether health beliefs are related to adherence to self-care regimen and HbA1c control	HbA1c & 11-item compliance self-report measure *T*-tests, Pearson's R correlations	HbA1c improved significantly in a subgroup of patients, but this improvement was not significantly associated with any health belief or with self-reported adherence
Zahednezhad *et al.* (2011) *Iran*	*N* = 120 Gender information not reported Age range 17-70 ^{Mean}Age & SD not reported	Type-II diabetics MHLC	To explore the relationship between memory, HLoC, and adherence to diabetes self-management regimen	GAS-SM Pearson's R correlations, multiple regression	A significant negative relationship was found between poor memory and adherence, and a significant positive relationship was found between iHLoC, other powerful HLoC and adherence

*Irrational Health Belief Scale (IHBS; Christensen, Moran & Wiebe, 1999)

3.2 Excluded Studies

As reported in figure 1, *n* = 11 records were excluded following title screening. A further 14 studies were excluded from the review following full-text screening for either adopting inappropriate design (*n* = 6) or sample (*n* = 5) for the topic of the current review, or if they were an unpublished dissertation (*n* = 1), a book chapter(*n* = 1), or a conference abstract (*n* = 1). A full list of the excluded studies can be found in appendix VI.

3.3 Critical Evaluation of Studies

The Appraisal tool for Cross-Sectional Studies (AXIS; Downes, Brennan, Williams, & Dean, 2016) was used to critically appraise the quality and risk of bias of the included studies. The checklist consists of five sections to assess the introduction, methodology, results, discussion and other considerations of cross-sectional studies. The AXIS was chosen on the basis that the eligible studies adopted cross-sectional designs to examine the relationship between HLoC and adherence to diabetes self-management regimens.

There is no numerical scoring option available for the AXIS tool, as the authors suggest that numerical assessment measures can be problematic given outputs from such checklists are not linear, making them difficult to weight and unpredictable at assessing quality (Downes *et al*., 2016) therefore the assessment is intended to be used qualitatively. However, for the purpose of the current review, the checklist was revised to allow for the numerical assessment of studies. A numerical value was assigned to each criteria as follows; 'yes' (3), 'somewhat' (2), 'no' (1) or 'not reported' (0), with the exception of criteria M and S which were reverse scored ('no' [3], 'somewhat' [2], 'yes' [1] or 'not reported' [0]) allowing a maximum possible score of 60 per study. Higher scores on the devised scoring system indicate superior quality of study. The adapted AXIS tool can be found in appendix V.

All eligible studies were evaluated by the first author and blindly inter-rated by a second rater. Quality ratings were compared, revealing interrater reliability of 95% across criteria. The quality ratings for each study can be found in table 5.

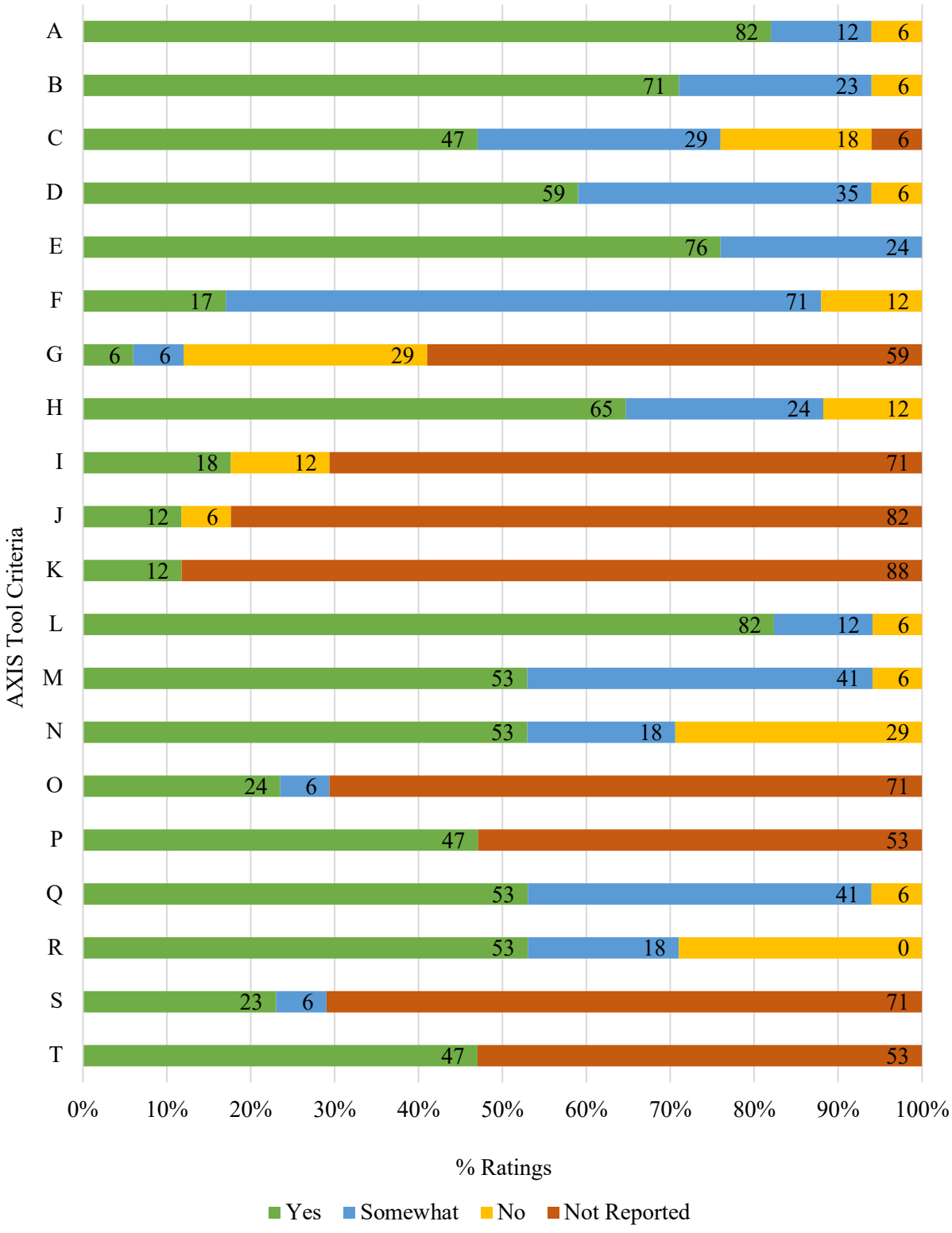
Table 5. *Critical Evaluation Ratings of Studies using the AXIS Tool*

	Criteria Items & Ratings																			
	Introduction			Methodology								Results					Discussion		Other	
	A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**	**K**	**L**	**M**	**N**	**O**	**P**	**Q**	**R**	**S**	**T**	***Total***
Akbargawi *et al.* (2017)	3	2	1	2	2	2	1	2	3	3	3	3	0	0	0	3	3	3	0	3	**39**
Alogna (1980)	2	1	1	2	3	1	0	3	3	0	0	1	0	0	0	1	1	1	0	0	**20**
Amsberg *et al.* (2009)	3	3	3	3	3	3	2	3	3	3	3	3	1	3	0	3	3	3	3	3	**54**
Habib & Durrani (2016)	3	3	0	2	3	2	0	3	2	3	2	3	0	0	0	3	2	1	0	0	**32**
Kacerovsky-Bielesz *et al.* (2009)	3	3	3	3	3	2	1	3	3	3	3	3	3	3	0	3	3	3	2	3	**53**
Kang & Hur (2019)	3	3	3	3	3	3	1	3	3	3	3	3	3	0	0	3	3	3	3	3	**52**
Klinovszky *et al.* (2019)	3	3	2	3	3	2	0	3	3	3	3	3	0	0	0	3	3	3	3	3	**46**
Kneckt *et al.* (1999)	3	3	2	1	3	2	0	3	3	3	3	2	0	0	3	3	3	1	0	3	**41**
Makarem *et al.* (2014)	1	2	2	2	3	2	0	2	3	3	3	2	0	0	0	3	3	1	0	0	**32**
Morowatisharifabad *et al.* (2010)	3	3	3	3	3	2	0	3	3	2	2	2	0	0	0	3	2	1	3	0	**38**
O'Hea *et al.* (2005)	2	3	2	2	2	1	3	3	3	3	3	3	0	0	0	3	2	3	0	0	**38**
Quiñones *et al.* (2018)	3	2	3	3	3	2	0	2	3	3	2	3	0	0	0	2	2	2	0	3	**38**
Schlenk & Hart (1984)	3	2	1	2	2	2	0	2	2	3	3	3	0	0	0	3	2	3	0	0	**33**

	Criteria Items & Ratings																			
	Introduction	Methodology										Results					Discussion		Other	
	A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**	**K**	**L**	**M**	**N**	**O**	**P**	**Q**	**R**	**S**	**T**	***Total***
Stenström *et al.* (1998)	3	3	3	3	3	2	0	3	3	3	3	3	0	0	3	3	2	3	0	3	**46**
Tillotson & Smith (1996)	3	3	3	3	3	3	1	2	2	3	3	3	3	0	0	3	3	3	0	0	**44**
Wooldridge *et al.* (1992)	3	3	3	3	3	2	1	3	3	3	2	2	1	1	0	3	2	2	0	0	**40**
Zahednezhad *et al.* (2011)	3	3	2	3	2	2	0	3	3	3	3	1	0	0	0	2	3	2	0	0	**35**
Mean	2.8	2.6	2.2	2.5	2.8	2.1	0.6	2.7	2.8	2.8	2.6	2.5	0.6	0.4	0.4	2.8	2.5	2.2	0.8	1.4	**39.6**

The total ratings per study ranged between 20 and 54 out of a total possible rating of 60, with a mean rating of 39.6. A summary of the percentage of ratings per criteria across studies can be found in figure 2.

Figure 2. *Summary of Criteria Ratings across Studies using the AXIS Tool*



With regards to studies which scored particularly well against the criteria of the AXIS tool, the three best studies (all scoring above 50 out of a possible 60 points) included Amsberg *et al.* (54), Kacerovsky-Bielesz *et al.* (53) and Kang and Hur (52). Reasons for these three studies ranking particularly well on the AXIS tool primarily stemmed from these studies employing sound methodology to investigate the relationship between HLoC and diabetes self-management. In fact, both Amsberg et al. and Kang and Hur were rated as having a near-perfect score with regards to methodology employed, both falling short only on criteria G, which rates the studies efforts to address and categorise non-responders.

The following sections provide a detailed critical evaluation of each section specified by the adapted AXIS tool.

3.3.1 Introduction Sections

This section refers to criterion A of the AXIS tool. Studies were awarded a score of 3 if they clearly outlined the aims and objectives of the study. The majority of studies included clearly specified aims and objectives, with a high mean score of 2.8. It is possible that the inclusion criteria for the current review played a part in the high scoring of this criterion by selecting only studies which clearly specified the aims of investigating the relationship between HLoC and diabetes self-management. One study (Makarem *et al*., 2014) failed to concisely outline the aims of the study, and two studies (Alogna, 1980; O'Hea *et al*., 2005) reported short introduction sections with vague aims and objectives.

3.3.2 Methodology Sections

This section refers to criteria B-K of the AXIS tool. The methodology across studies was varied. Regarding criterion B, the majority of studies adopted a cross-sectional design appropriate to investigating the relationship between HLoC and adherence to diabetes self-management regimens (71%). It is possible that the inclusion criteria for the current review played a role in the high scoring of criterion B by selecting only studies which employed an appropriate design to investigate the relationship between HLoC and diabetes self-management. However, one study (Alogna, 1980) scored poorly on study design as it failed to report the type of design used and provided limited information to allow the reader to understand the design of the study.

Criterion C examined the sample size of studies. Only two studies (Kang & Hur, 2019; Morowatisharifabad *et al.,* 2010) reported a power analysis to show consideration had been paid

to determine an appropriate sample size. Ratings for the remaining studies were determined by conducting a power analysis where possible with the information reported. If the study included a sample of sufficient size to detect small effects (Cohen, 1988; Cohen's $d = .2$), it was awarded a rating of 3. For studies sufficiently powered to detect medium effects, they were awarded a rating of 2 (Cohen's $d = .5$). A rating of 1 was awarded to studies which were insufficiently powered to detect large effects (Cohen's $d = .8$). A little under half of studies (47%) reviewed included sample sizes which were sufficiently powered to detect small effect sizes.

Ratings for criterion D concerning the target population were more varied. The majority of studies (59%) reported a clearly defined target population, however other studies failed to clearly describe the intended population under investigation.

Criterion E evaluated the appropriateness of the sample compared to the target population. The vast majority of studies (76%) recruited from a sample frame which was likely to obtain participants who were representative of the target population, i.e. diabetes outpatient clinics or other related healthcare settings. Four of the reviewed studies only somewhat satisfied this criterion as the sample frames they recruited from used convenience sampling methods (Albargawi *et al*., 2017), or were recruited within a particularly narrow sociodemographic or clinical setting (O'Hea *et al*., 2005; Schlenk & Hart; Zahednezhad *et al.*, 2011). Regarding criterion F, studies which made efforts to recruit participants from more than one geographic site / clinic were regarded as employing a selection process that was likely to recruit participants representative of the target population, whereas those which only recruited from one site / clinic were deemed to somewhat satisfy this criterion.

Regarding criterion G, the majority of studies failed to report efforts to understand non-response (59%). This information may have been particularly interesting to analyse, as it is possible that non-response may be related to non-adherence in this setting. Criterion H evaluated the appropriateness of the measures adopted to investigate the key study variables. It is possible that the inclusion criteria for the current review played a part in the high scoring of criterion H by selecting only studies which clearly specified appropriate measures of HLoC and diabetes self-management. However, it should be noted that such measures were primarily self-reported therefore it is not possible to be sure of accuracy.

Criterion I allowed for the exploration of the validity and reliability of measures used to determine HLoC and diabetes self-management adherence. Ratings on this criterion were more varied, given the heterogeneity of the measures employed across studies. Regarding criterion J, all studies reported their selected *p* value for determining statistical significance, except Alogna (1980) which failed to report most aspects of the statistical analysis and other methodology.

Finally, criterion K assessed the adequecy of the methodology descriptions outlined by studies. In general, studies rated poorly on this criterion, as many failed to report key details, such as information regarding the statistical analyses methods adopted, which would allow for the study to be replicated by future researchers.

3.3.3 Results Sections

This section refers to criteria L-P of the AXIS tool. The majority of studies rated well on criterion L, revealing that 82% of studies adequately described the basic data. Regarding criterion O, most studies failed to report on the internal consistency of their results. However, studies which used validated measures, such as the MHLC or SDSCA are reported to have good internal consistency, therefore it could be surmised that the internal consistencies of such studies results are likely to be good. Stenström *et al.* (1998) explicitly tested and reported the internal consistency of their results by selecting a proportion of the original sample (*n*=25) to retest two weeks later. The results revealed test-retest reliabilities, as measured by Cronbach's alpha, of .65 for iHLoC, .75 for powerful others HLoC and .77 for chance HLoC. Similarly to criterion K, many of the studies reviewed failed to provide specific details of the analyses, resulting in poor ratings across studies for this criterion.

With regards to effect sizes found by studies, some studies reported effect sizes whereas others reported the required information for the reader to calculate the effect size independently. Three studies (Alogna, 1980; Amsberg *et al.*, 2009; and Quiñones *et al.*, 2018) all used a *t*-tests to compare HLoC in compliant and non-compliant groups. However, unfortunately these studies failed to report the statistics (*t* value and *df* or means and SDs) required to calculate the effect sizes, instead they chose simply to report the significance (*p* value) of their *t*-tests.

Habib and Durrani (2016), Kang and Hur (2019), Klinovszky *et al.* (2019), Kneckt *et al.* (1999), Makarem *et al.* (2014), Morowatisharifabad *et al.* (2010), O'Hea *et al.* (2005), Schlenk and Hart (1984), Stenström *et al.* (1998), Tillotson and Smith (1996), and Zahednezhad *et al.* (2011) all either reported

Pearson's *R* effect sizes, or the information required to calculate them (*t* value and *df*). According to Cohen (1980) are interpreted as follows; r = >.1 indicates small effects, >.3 indicates medium effects, and > .5 indicates large effects.

For Akbargawi *et al.* (2017) and Kacerovsky-Bielesz *et al.* (2009), F^2 is used to determine effect size (Cohen, 1988). F^2 is calculated as follows:

$$F^2 = \frac{R^2_{inc}}{1-R^2_{inc}}$$

According to Cohen (1988), f^2 = >.02 indicates a small effect, >.15 indicates a medium effect, and >.35 indicates large effects.

Studies yielded a range of effect sizes for different variables from small to large effects. A summary of the effect sizes of the relevant statistically significant results found in each study can be found in table 6.

Table 6. *Summary of Effect Sizes found in each Study*

Study	Effect Size	
Akbargawi *et al.* (2017)	iHLoC and adherence to blood glucose monitoring: f^2 = .2	Medium
	iHLoC and adherence to diet: f^2 = .2	Medium
Alogna (1980)	Unknown	Unknown
Amsberg *et al.* (2009)	Unknown	Unknown
Habib & Durrani (2016)	iHLoC and adherence to diet: r = .2	Small
	iHLoC and adherence to exercise: r = .1	Small
	dHLoC and adherence to diet: r = .3	Medium
	dHLoC and adherence to medication: r = .2	Small
	cHLoC and adherence to diet: r = -.2	Small
	cHLoC and adherence to exercise: r = -.3	Medium
Kacerovsky-Bielesz *et al.* (2009)	f^2 = .2	Medium
Kang & Hur (2019)	iHLoC and adherence to medication: r = .1	Small
	oHLoC and adherence to medication: r = .1	Small

	cHLoC and adherence to medication: *r* = .1	Small
Klinovszky *et al.* (2019)	iHLoC and adherence to blood glucose monitoring: *r* = .4	Medium
	iHLoC and adherence to medication: *r* = .2	Small
	oHLoC and adherence to blood glucose monitoring: *r* = .3	Medium
Kneckt *et al.* (1999)	iDLoC and adherence to dental regimen: *r* = .1	Small
Makarem *et al.* (2014)	iHLoC and adherence to diabetes regimen: *r* = .2	Small
	dHLoC and adherence to diabetes regimen: *r* = .2	Small
	oHLoC and adherence to diabetes regimen: *r* = .2	Small
	cHLoC and adherence to diabetes regimen: *r* = .3	Medium
Morowatisharifabad *et al.* (2010)	iDLoC and adherence to diabetes regimen in women: *r* = .5	Large
	oDLoC and adherence to diabetes regimen in women: *r* = .3	Medium
	iDLoC and type-II diabetes regimen adherence: *r* = .3	Medium
	dDLoC and type-II diabetes regimen adherence: *r* = .2	Small
O'Hea *et al.* (2005)	iHLoC and HbA1c: *r* = .6	Large
Quiñones *et al.* (2018)	Unknown	Unknown
Schlenk & Hart (1984)	iHLoC and adherence to diabetes regimen: *r* = .5	Large
	oHLoC and adherence to diabetes regimen: *r* = .5	Large
	cHLoC and adherence to diabetes regimen: *r* = .5	Large
Stenström *et al.* (1998)	DLoC and HbA1c: *r* = .5	Large
Tillotson & Smith (1996)	iDLoC and weight control regiment adherence: *r* = .1	Small
Wooldridge *et al.* (1992)	No statistically significant results	N/A
Zahednezhad *et al.* (2011)	iHLoC and adherence to diabetes regimen: *r* = .2	Small
	oHLoC and adherence to diabetes regimen: *r* = .3	Medium

3.3.4 Discussion Sections

This section refers to criteria Q and R of the AXIS tool. Approximately half of the studies scored well on these criteria by reporting well-justified conclusions based on the results and discussing the relevant limitations of their respective studies.

3.3.5 Other Evaluations

This section refers to criteria S and T of the AXIS tool, evaluating any potential biases stemming from funding or conflicts of interest, as well as appropriate ethical approvals for conducting the study. Surprisingly, few studies reported any details to inform these criteria, despite it being good research practice to do so.

4. DISCUSSION

The aim of the review was to develop a better understanding of the theoretical underpinnings of adherence to diabetes self-management regimens, as this may help to guide clinical practice by informing both patient and clinician on the likelihood of adhering to the recommended treatment plan based on existing health-related beliefs.

The current review expands upon previously conducted reviews (Strudler Wallston, & Wallston, 1978; Chung, Cheung, & Lo, 2016; and Náfrádi, Nakamoto, & Schulz, 2017). The findings are in line with early research conducted by Strudler Wallston and Wallston (1978), demonstrating that the relationship between iHLoC and health behaviours can be found when examining diabetes self-management specifically. Interestingly, the effect sizes determining the strength of the relationship between HLoC and diabetes self-management found in the current review are greater to those examining health behaviours more generally, such as those found by Cheng, Cheung and Lo (2016). It is possible that this finding relates to the high self-management burden of diabetes care compared to other health conditions.

4.1 Summary of Findings

In relation to the review question regarding the relationship between HLoC and diabetes self-management adherence, the majority of studies report evidence of iHLoC being positively related to adherence to diabetes self-management regimens, i.e., the more internal one's HLoC, the more likely one is to adhere to diabetes self-management regimens. The key findings are outlined as follows.

Studies reported various relationships between HLoC domains and aspects of adherence to diabetes self-management. In general, studies found evidence to suggest that stronger iHLoC beliefs were related to greater compliance with various aspects of diabetes self-management (Albargawi *et al*., 2017; Alogna, 1980; Habib & Durrani, 2016; Klinovszky *et al.,* 2019;

Makarem *et al*., 2014; Morowatisharifabad *et al.,* 2010; O'Hea *et al.*, 2005; Schlenk & Hart, 1984; Stenström *et al.*, 1998; Zahednezhad *et al.*, 2011; Tillotson & Smith, 1996), however the strength of this evidence varied and was limited by various methodological or statistical flaws. For example, the main conclusion of a study by Alogna (1980) was that compliant patients exhibited stronger iHLoC beliefs than non-compliant patients, however the study failed to report any empirical data, thus it is not possible to assess the validity of these conclusions. Stronger eHLoC beliefs were also found to be related to poorer adherence to diabetes self-management regimens Quiñones *et al.* (2018)

Conflicting evidence regarding HLoC beliefs was also found. Kang and Hur (2019) found no significant relationships between DLoCs domains and diabetes medication adherence, suggesting that increased self-efficacy was more important in determining diabetes self-management than HLoC beliefs. Similarly, Amsberg *et al*. (2009) failed to find any effects of HLoC on diabetes self-management, however this may have been due to design flaws such as insufficient numbers to adequately power the analysis, and Kneckt *et al.* (1999) only found weak correlations between DLoC beliefs correlated diabetes self-management adherence ($r = 0.17$, $p = 0.052$), and found no associations between DLoC beliefs and oral health behaviour. Finally, Wooldridge *et al.* (1992) found that while HbA1c improved significantly over a course of self-management in a subgroup of patients, this improvement was not significantly associated with any health belief or with self-reported adherence.

Interestingly, some studies found interactions between effects of HLoC beliefs and gender. Kacerovsy-Bielesz *et al.* (2009) found that stronger 'doctor' HLoC beliefs were related to poor blood glucose control in females, but not in males. Contrary to his finding, Morowatisharifabad *et al.* (2010) found no significant correlations were found diabetes self-management adherence and DLoC subscales among men, but 'internal' ($r = 0.451$) and 'doctors' ($r = 0.251$) DLoC were positively correlated with adherence among women.

4.2 Limitations of Current Review

One of the main limitations of the current review is that the AXIS tool also fails to provide a mechanism for evaluating the strength of the relationship between the key variables of each study, therefore it is only possible to comment on the strength of the relationship between HLoC and diabetes self-management qualitatively. The AXIS tool also fails to account for extraneous variables which might interact with the relationship between HLoC and diabetes

self-management. For example, Peryot *et al.* (2005) raised the argument that psychosocial problems, such as socioeconomic deprivation, may help to explain poor diabetes self-management and may indeed mediate the effects of HLoC on self-management behaviours. Similarly, the AXIS tool fails to account for cultural biases within the literature, which for this particular review question is problematic given the variety of countries producing relevant research on the topic of HLoC in diabetes self-management.

Conducting a meta-analysis of the literature could have allowed for further critical and statistical analysis of the included studies by combining the results of similar studies. Unfortunately, the heterogeneity of the included studies would have made conducting a meta-analysis impossible (Fagard, Staessen, & Thijs, 1996).

High quality systematic reviews such as those published in the Cochrane database, often use advanced software programmes such as Archie and RevMan, and employ teams of researchers to conduct thorough searches of the literature and analyse results (Deeks, Bossuyt, & Gatsonis (editors), The Cochrane Collaboration, 2013). Cochrane recommends the use of Archie 4.10 and RevMan 5.3 software packages to enable researchers to meet the demands of producing high quality systematic reviews within the context of healthcare. The same standard of scrutiny has not been employed by the current review due to lack of feasibility, however future research could consider adopting the same premise as the current review however employ greater software to conduct the review.

4.3 Clinical Implications

The current review sheds light on the underpinnings of diabetes self-management. It is hoped that the current review highlights the significance of exploring HLoC as a potentially important factor in judging the likelihood of patients adhering to diabetes self-management programmes, and as such pre-empting the need for additional support if required. This may involve redesigning out-patients services to include pre-treatment screening measures of HLoC help identify patients who may require additional support in adhering to their recommended treatment plan. In the longer term, this could both improve the overall health of the patient by improving their likelihood of adhering to recommended plan, and also help to relieve the financial burden on services stemming from poorly managed diabetes.

4.4 Directions for Future Research

Future systematic reviews could seek to rectify the limitations of the current review by specifically assessing the strength of the relationships between HLoC beliefs and adherence to diabetes self-management. It would also be interesting to assess the stability of HLoC beliefs over the course of a diabetes self-management regimen, as it is possible that patients' beliefs may change as they adapt to managing a chronic health condition. Further research is needed to assess for this possibility, adopting longitudinal design methodology.

4.5 Conclusion

The current review consolidated and critically appraised the current evidence base surrounding the relationship between HLoC and diabetes self-management. It highted the discrepancies and problematic heterogeneity across the measurement of diabetes self-management, and therefore the results of the current review should be considered in the light of these. Despite the limitations outlined, it is evident that HLoC beliefs play an important role in adherence to diabetes self-management. This review may assist clinicians in supporting those who are required to self-manage aspects of their healthcare, however clinicians should always assess the suitability of self-management interventions on an individual basis.

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Appendix I. Author Guidelines for the British Journal of Health Psychology

Author Guidelines for the British Journal of Health Psychology

The aim of the British Journal of Health Psychology is to provide a forum for high quality research, including Registered Reports, relating to health and illness. The scope of the journal includes all areas of health psychology as outlined in the Journal Overview.

The types of paper invited are:

- papers reporting original empirical investigations, using either quantitative or qualitative methods, including reports of interventions in clinical and non-clinical populations;
- theoretical papers which report analyses on established theories in health psychology;
- we particularly welcome review papers, which should aim to provide systematic overviews, evaluations and interpretations of research in a given field of health psychology (narrative reviews will only be considered for editorials or important theoretical discourses); and
- methodological papers dealing with methodological issues of particular relevance to health psychology.

Authors who are interested in submitting papers that do not fit into these categories are advised to contact the editors who would be very happy to discuss the potential submission. All papers published in The British Journal of Health Psychology are eligible for Panel A: Psychology, Psychiatry and Neuroscience in the Research Excellence Framework (REF).

1. Circulation

The circulation of the Journal is worldwide. Papers are invited and encouraged from authors throughout the world.

2. Length

Papers describing quantitative research (including reviews with quantitative analyses) should be no more than 5000 words (excluding the abstract, reference list, tables and figures). Papers describing qualitative research (including reviews with qualitative analyses) should be no more than 6000 words (including quotes, whether in the text or in tables, but excluding the abstract, tables, figures and references). In exceptional cases the Editor retains discretion to publish papers beyond this length where the clear and concise expression of the scientific content requires greater length (e.g., explanation of a new theory or a substantially new method). Authors must contact the Editor prior to submission in such a case.

3. Editorial policy

The Journal receives a large volume of papers to review each year, and in order to make the process as efficient as possible for authors and editors alike, all papers are initially examined by the Editors to ascertain whether the article is suitable for full peer review. In order to qualify for full review, papers must meet the following criteria:

- the content of the paper falls within the scope of the Journal;
- the methods and/or sample size are appropriate for the questions being addressed;
- research with student populations is appropriately justified; and

- the word count is within the stated limit for the Journal (i.e. 5000 words, or 6,000 words for qualitative papers)

4. Submission and reviewing

All manuscripts must be submitted via Editorial Manager. The Journal operates a policy of anonymous (double blind) peer review. We also operate a triage process in which submissions that are out of scope or otherwise inappropriate will be rejected by the editors without external peer review to avoid unnecessary delays. Before submitting, please read the terms and conditions of submission and the declaration of competing interests. You may also like to use the Submission Checklist to help your prepare your paper.

By submitting a manuscript to or reviewing for this publication, your name, email address, and affiliation, and other contact details the publication might require, will be used for the regular operations of the publication, including, when necessary, sharing with the publisher (Wiley) and partners for production and publication. The publication and the publisher recognize the importance of protecting the personal information collected from users in the operation of these services, and have practices in place to ensure that steps are taken to maintain the security, integrity, and privacy of the personal data collected and processed. You can learn more at https://authorservices.wiley.com/statements/data-protection-policy.html.

5. Manuscript requirements

- Contributions must be typed in double spacing with wide margins. All sheets must be numbered.
- Manuscripts should be preceded by a title page which includes a full list of authors and their affiliations, as well as the corresponding author's contact details. You may like to use this template. When entering the author names into Editorial Manager, the corresponding author will be asked to provide a CRediT contributor role to classify the role that each author played in creating the manuscript. Please see the Project CRediT website for a list of roles.
- For articles containing original scientific research, a structured abstract of up to 250 words should be included with the headings: Objectives, Design, Methods, Results, Conclusions. Review articles should use these headings: Purpose, Methods, Results, Conclusions. As the abstract is often the most widely visible part of your paper, it is important that it conveys succinctly all the most important features of your study. You can save words by writing short, direct sentences. Helpful hints about writing the conclusions to abstracts can be found here.
- Statement of Contribution: All authors are required to provide a clear summary of ‘what is already known on this subject?’ and ‘what does this study add?’. Authors should identify existing research knowledge relating to the specific research question and give a summary of the new knowledge added by your study. Under each of these headings, please provide 2-3 (maximum) clear outcome statements (not process statements of what the paper does); the statements for 'what does this study add?' should be presented as bullet points of no more than 100 characters each. The Statement of Contribution should be a separate file.
- Conflict of interest statement: We are now including a brief conflict of interest statement at the end of each accepted manuscript. You will be asked to provide information to generate this statement during the submission process.
- The main document must be anonymous. Please do not mention the authors’ names or affiliations (including in the Method section) and always refer to any previous work in the third person.

- Tables should be typed in double spacing, each on a separate page with a self-explanatory title. Tables should be comprehensible without reference to the text. They should be placed at the end of the manuscript, but they must be mentioned in the text.
- Figures can be included at the end of the document or attached as separate files, carefully labelled in initial capital/lower case lettering with symbols in a form consistent with text use. Unnecessary background patterns, lines and shading should be avoided. Captions should be listed on a separate sheet. The resolution of digital images must be at least 300 dpi. All figures must be mentioned in the text.
- For reference citations, please use APA style. Particular care should be taken to ensure that references are accurate and complete. Give all journal titles in full and provide doi numbers where possible for journal articles.

For example:
Author, A., Author, B., & Author, C. (1995). Title of book. City, Country: Publisher.
Author, A. (2013). Title of journal article. Name of journal, 1, 1-16. doi: 10.1111/bjep.12031

- SI units must be used for all measurements, rounded off to practical values if appropriate, with the imperial equivalent in parentheses.
- In normal circumstances, effect size should be incorporated.
- Authors are requested to avoid the use of sexist language.
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- Manuscripts describing clinical trials are encouraged to submit in accordance with the CONSORT statement on reporting randomised controlled trials.
- Manuscripts reporting systematic reviews and meta-analyses are encouraged to submit in accordance with the PRISMA statement.
- Manuscripts reporting interventions are encouraged to describe them in accordance with the TIDieR checklist.

If you need more information about submitting your manuscript for publication, please email Hannah Wakley, Managing Editor (bjhp@wiley.com) or phone +44 (0) 116 252 9504.

6. Supporting information

We strongly encourage submission of protocol papers or trial registration documents, where these are in the public domain, to allow reviewers to assess deviations from these protocols. This will result in reviewers being unblinded to author identity.

Supporting Information can be a useful way for an author to include important but ancillary information with the online version of an article. Examples of Supporting Information include appendices, additional tables, data sets, figures, movie files, audio clips, and other related nonessential multimedia files. Supporting Information should be cited within the article text, and a descriptive legend should be included. Please indicate clearly on submission which material is for online only publication. It is published as supplied by the author, and a proof is not made available prior to publication; for these reasons, authors should provide any Supporting Information in the desired final format.

For further information on recommended file types and requirements for submission, please visit the Supporting Information page on Author Services.

7. OnlineOpen

OnlineOpen is available to authors of primary research articles who wish to make their article available to non-subscribers on publication, or whose funding agency requires grantees to archive the final version of their article. With OnlineOpen, the author, the author's funding agency, or the author's institution pays a fee to ensure that the article is made available to non-subscribers upon publication via Wiley Online Library, as well as deposited in the funding agency's preferred archive. A full list of terms and conditions is available on Wiley Online Library.

Any authors wishing to send their paper OnlineOpen will be required to complete the payment form.

Prior to acceptance there is no requirement to inform an Editorial Office that you intend to publish your paper OnlineOpen if you do not wish to. All OnlineOpen articles are treated in the same way as any other article. They go through the journal's standard peer-review process and will be accepted or rejected based on their own merit.

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If you select the OnlineOpen option and your research is funded by The Wellcome Trust and members of the Research Councils UK (RCUK) or the Austrian Science Fund (FWF) you will be given the opportunity to publish your article under a CC-BY licence supporting you in complying with your Funder requirements. For more information on this policy and the Journal's compliant self-archiving policy please visit our Funder Policy page.

10. Colour illustrations

Colour figures may be published online free of charge; however, the journal charges for publishing figures in colour in print. If the author supplies colour figures at Early View publication, they will be invited to complete a colour charge agreement in RightsLink for Author Services. The author will have the option of paying immediately with a credit or debit card, or they can request an invoice. If the author chooses not to purchase colour printing, the figures will be converted to black and white for the print issue of the journal.

11. Pre-submission English-language editing

Authors for whom English is a second language may choose to have their manuscript professionally edited before submission to improve the English. A list of independent suppliers of editing services can be found in Author Services. All services are paid for and arranged by the author and use of one of these services does not guarantee acceptance or preference for publication.

12. The Later Stages

The corresponding author will receive an email alert containing a link to a web site. The proof can be downloaded as a PDF (portable document format) file from this site. Acrobat Reader will be required in order to read this file. This software can be downloaded (free of charge) from Adobe's web site. This will enable the file to be opened, read on screen and annotated direct in the PDF. Corrections can also be supplied by hard copy if preferred. Further instructions will be sent with the proof. Excessive changes made by the author in the proofs, excluding typesetting errors, will be charged separately.

13. Early View

British Journal of Health Psychology is covered by the Early View service on Wiley Online Library. Early View articles are complete full-text articles published online in advance of their publication in a printed issue. Articles are therefore available as soon as they are ready, rather than having to wait for the next scheduled print issue. Early View articles are complete and final. They have been fully reviewed, revised and edited for publication, and the authors' final corrections have been incorporated. Because they are in final form, no changes can be made after online publication. The nature of Early View articles means that they do not yet have volume, issue or page numbers, so they cannot be cited in the traditional way. They are cited using their Digital Object Identifier (DOI) with no volume and

issue or pagination information. Eg Jones, A.B. (2010). Human rights Issues. Journal of Human Rights. Advance online publication. doi:10.1111/j.1467-9299.2010.00300.x

Further information about the process of peer review and production can be found in this document. What happens to my paper? Appeals are handled according to the procedure recommended by COPE.

Appendix II. Prospero Registration of Systematic Review Topic

UNIVERSITY of York
Centre for Reviews and Dissemination

Systematic review

1. Review title

Give the working title of the review, for example the one used for obtaining funding. Ideally the title should state succinctly the interventions or exposures being reviewed and the associated health or social problems. Where appropriate, the title should use the PI(E)COS structure to contain information on the Participants, Intervention (or Exposure) and Comparison groups, the Outcomes to be measured and Study designs to be included.

The impact of health locus of control (HLoC) in diabetes self-management: a systematic review

2. Original language title

For reviews in languages other than English, this field should be used to enter the title in the language of the review. This will be displayed together with the English language title.

Not applicable

3. Anticipated or actual start date.

Give the date when the systematic review commenced or is expected to commence.

11/11/2019

4. Anticipated completion date

Give the date by which the review is expected to be completed.

02/03/2020

5. Stage of review at time of this submission

Indicate the stage of progress of the review by ticking the relevant Started and Completed boxes. Additional information may be added in the free text box provided.

Please note: Reviews that have progressed beyond the point of completing data extraction at the time of initial registration are not eligible for inclusion in PROSPERO. Should evidence of incorrect status and/or completion date being supplied at the time of submission come to light, the content of the PROSPERO record will be removed leaving only the title and named contact details and a statement that inaccuracies in the stage of the review date had been identified.

This field should be updated when any amendments are made to a published record and on completion and publication of the review. If this field was pre-populated from the initial screening questions then you are not able to edit it until the record is published.

The review has not yet started: No

Review stage	Started	Completed
Preliminary searches	Yes	No
Piloting of the study selection process	No	No

Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

Provide any other relevant information about the stage of the review here (e.g. Funded proposal, protocol not yet finalised).

Not applicable

6. Named contact

The named contact acts as the guarantor for the accuracy of the information presented in the register record.

Fabia Cientanni

Email salutation (e.g. "Dr Smith" or "Joanne") for correspondence:
Fabia

7. Named contact email

Give the electronic mail address of the named contact.

f.cientanni@nhs.net

8. Named contact address

Give the full postal address for the named contact.

Lynebank Hospital, Halbeath Road, Dunfermline,
KY11 4UW

9. Named contact phone number

Give the telephone number for the named contact, including international dialing code.

+447477580824

10. Organisational affiliation of the review

Full title of the organisational affiliations for this review and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

NHS Fife

Organisation web address:
https://www.nhsfife.org/nhs/index.cfm

11. Review team members and their organisational affiliations

Give the title, first name, last name and the organisational affiliations of each member of the review team. Affiliation refers to groups or organisations to which review team members belong.

Miss Fabia Cientanni, NHS Fife; Dr Frances Baty, NHS Fife; Professor Matthias Schwannauer, University of Edinburgh; Professor Kevin Power, NHS Tayside

12. Funding sources/sponsors

Give details of the individuals, organizations, groups or other legal entities who take responsibility for initiating, managing, sponsoring and/or financing the review. Include any unique identification numbers assigned to the review by the individuals or bodies listed.

University of Edinburgh

13. Conflicts of interest

List any conditions that could lead to actual or perceived undue influence on judgements concerning the main topic investigated in the review.

None

14. Collaborators

Give the name and affiliation of any individuals or organisations who are working on the review but who are not listed as review team members.

Not applicable

15. Review question

State the question(s) to be addressed by the review, clearly and precisely. Review questions may be specific or broad. It may be appropriate to break very broad questions down into a series of related more specific questions. Questions may be framed or refined using PI(E)COS where relevant.

What is the impact of Health Locus of Control (HLoC) in diabetes self-management?

16. Searches

State the sources that will be searched. Give the search dates, and any restrictions (e.g. language or publication period). Do NOT enter the full search strategy (it may be provided as a link or attachment.)

Online scientific databases will be searched in order to identify studies relevant to answering the systematic review question. A publication period was set from the year 2000 to present date as to fit with the development of the concept and definition of Health Locus of Control (HLoC). Searches will be re-run immediately prior to the final analysis in order to ensure that the most up-to-date literature is reviewed.
Unpublished studies will not be sought.

17. URL to search strategy

Give a link to a published pdf/word document detailing either the search strategy or an example of a search strategy for a specific database if available (including the keywords that will be used in the search strategies) or upload your search strategy. Do NOT provide links to your search results.

https://www.crd.york.ac.uk/PROSPEROFILES/159603_STRATEGY_20191122.pdf

Alternatively, upload your search strategy to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.

Do not make this file publicly available until the review is complete

18. Condition or domain being studied

Give a short description of the disease, condition or healthcare domain being studied. This could include health and wellbeing outcomes.

The condition being studied is Diabetes Mellitus (commonly known as Diabetes), a chronic disease which effects the way in which the body metabolises sugars. A large component of treatment for diabetes involves self-management through a healthy controlled diet and exercise. This can often require a considerable lifestyle change for those diagnosed. Insulin injections can also be required, which again relies heavily on patient self-management. In fact, it is estimated that 95% of diabetes management is self-management. The review aims to study one potentially important psychological theory related to the self-management of diabetes self-management, Health Locus of Control (HLoC) theory. HLoC theory offers an explanation to understand health-related decision making, postulating that expectancies are placed on the degree of control one has over ones' health outcomes.

19. Participants/population

Give summary criteria for the participants or populations being studied by the review. The preferred format includes details of both inclusion and exclusion criteria.

Participants will include people diagnosed with Diabetes. The inclusion and exclusion criteria are as follows:

Inclusion Criteria:
1. Adults (aged over 16 years of age) diagnosed with Diabetes (type I or II)
2. Studies investigating adherence to self-management-based interventions for diabetes as a dependent variable (any treatment that prescribes an active involvement from the patient in the form of a change in lifestyle or health behaviour
3. Studies completed after the year 2000

Exclusion Criteria
1. Adolescents (under 18 years of age)
2. Non-quantitative studies
3. Prison samples
4. In-patient samples
5. Medication-adherence studies

20. Intervention(s), exposure(s)

Give full and clear descriptions or definitions of the nature of the interventions or the exposures to be reviewed.

A large component of treatment for diabetes involves self-management of the condition through a healthy controlled diet and exercise. This can often require a considerable lifestyle change for those diagnosed. For the purpose of the current systematic review, the above description serves as a definition for "self-

management" of diabetes.

21. Comparator(s)/control

Where relevant, give details of the alternatives against which the main subject/topic of the review will be compared (e.g. another intervention or a non-exposed control group). The preferred format includes details of both inclusion and exclusion criteria.

Not applicable

22. Types of study to be included

Give details of the types of study (study designs) eligible for inclusion in the review. If there are no restrictions on the types of study design eligible for inclusion, or certain study types are excluded, this should be stated. The preferred format includes details of both inclusion and exclusion criteria.

Inclusion Criteria:
1. Studies investigating adherence to self-management-based interventions as a dependent variable (any treatment that prescribes an active involvement from the patient in the form of a change in lifestyle or health behaviour. Active participation rather than passive adherence e.g. medication only interventions, aspects of self-management)
2. Studies completed after the year 2000

Exclusion Criteria:
1. Non-quantitative studies
2. Prison samples
3. In-patient samples
4. Medication-adherence studies

23. Context

Give summary details of the setting and other relevant characteristics which help define the inclusion or exclusion criteria.

Self-management of diabetes would usually occur within the community i.e. not within hospital settings, as hospital-delivered interventions are considered to be qualitatively different from at-home required / prescribed lifestyle changes.

24. Main outcome(s)

Give the pre-specified main (most important) outcomes of the review, including details of how the outcome is defined and measured and when these measurements are made, if these are part of the review inclusion criteria.

The most important outcome of the current systematic review is to understand the relationship between HLoC and diabetes self-management as measured by diabetes (condition) control following a prescribed course of healthy diet, exercise, and blood glucose monitoring. Diabetes control might be measured by blood samples in certain studies, which help to produce an idea of how well individuals are self-managing their condition. In other studies, diabetes control might be measured more subjectively through self-reported measures.

Timing and effect measures
See above

25. Additional outcome(s)
List the pre-specified additional outcomes of the review, with a similar level of detail to that required for main outcomes. Where there are no additional outcomes please state 'None' or 'Not applicable' as appropriate to the review.

None

Timing and effect measures
Not applicable

26. Data extraction (selection and coding)
Describe how studies will be selected for inclusion. State what data will be extracted or obtained. State how this will be done and recorded.

Study Selection:
Studies will be selected manually for inclusion by the primary reviewer, who will at first screen study titles, then abstracts, before further screening against inclusion / exclusion criteria. Selected studies will then be assessed for eligibility by a second reviewer will screen records independently. The results of this process will then be discussed between reviewers. Any disagreements regarding study selection will be raised with a third independent reviewer, who will be blinded to reviewer one and two's judgement on the matter, and who will hold the right to the final decision.

The selected studies will be recorded by exporting and storing relevant studies using Mendeley Desktop software.

Data Extraction:
Data regarding study design and methodology, data regarding participant demographics and treatment outcome (including effect sizes) will be extracted from the relevant studies by the reviewer and exported into a table in a Microsoft Word document. Data extraction will be completed by one reviewer, however will be checked="checked" value="1" by a second reviewer. The results of this process will then be discussed between reviewers. Any disagreements regarding data extraction will be raised with a third independent reviewer, who will be blinded to reviewer one and two's judgement on the matter, and who will hold the right to the final decision.

Missing data will be handled by at first contacting the study authors for further information. If this proves unsuccessful, missing data will be highlighted and discussed as a limitation of the systematic review.

Extracted data will be recorded and managed using Microsoft Word software.

27. Risk of bias (quality) assessment
Describe the method of assessing risk of bias or quality assessment. State

which characteristics of the studies will be assessed and any formal risk of bias tools that will be used.

A risk of bias assessment will be conducted using the Cochrane Collaboration's Tool for Assessing the Risk of Bias to investigate internal validity. The characteristics which will be assessed for bias will include measures of HLoC and outcome measures of diabetes management (including effect sizes). Heterogeneity of study characteristics (study design and the characteristics of the study population) will be reported. The assessment will be completed at outcome level. The results of this assessment will inform the data synthesis qualitatively and will be discussed in the writing of the report.

One reviewer will conduct the quality assessment, however will be checked by a second reviewer. The results of this process will then be discussed between reviewers. Any disagreements regarding quality assessment will be raised with a third independent reviewer, who will be blinded to reviewer one and two's judgement on the matter, and who will hold the right to the final decision.

28. Strategy for data synthesis

*Provide details of the planned synthesis including a rationale for the methods selected. This **must not be generic text** but should be **specific to your review** and describe how the proposed analysis will be applied to your data.*

The criteria under which the data will be synthesised is based on recommendations published for data- synthesis in systematic reviews of studies concerning outcome prediction models (Van den Berg et al., 2013). Sample size of studies will be considered against 'Event per Variable' (EPV; number of predictors assessed compared with the number of events). Statistical power of 10 studies will be assessed using the recommended EPV rule of statistical power for Cox regression models of 10 events per candidate predictor, as determined by the smallest group (Bradley et al., 2019).

Data concerning HLoC outcome, type of self-managed intervention prescribed (e.g. diet or exercise regime), and diabetes control outcome (including effect sizes) will be synthesised, to produce an understanding of the impact of HLoC on the self-management of diabetes. The method of combining individual study data will involve manually tabulating relevant extracted data using Microsoft Word software. Forest plots / risk-of-bias tables will then be produced, and the results of the analysis will be summarised qualitatively.

29. Analysis of subgroups or subsets

State any planned investigation of 'subgroups'. Be clear and specific about which type of study or participant will be included in each group or covariate investigated. State the planned analytic approach.

Not applicable

30. Type and method of review

Select the type of review and the review method from the lists below. Select the

health area(s) of interest for your review.

Type of review Cost effectiveness No
Diagnostic No
Epidemiologic No
Individual patient data (IPD) meta-analysis No
Intervention No
Meta-analysis No
Methodology No
Narrative synthesis No
Network meta-analysis No
Pre-clinical No
Prevention No
Prognostic No
Prospective meta-analysis (PMA) No
Review of reviews No
Service delivery No
Synthesis of qualitative studies No
Systematic review Yes
Other No
Health area of the review Alcohol/substance misuse/abuse No
Blood and immune system No
Cancer No
Cardiovascular No
Care of the elderly No
Child health No
Complementary therapies No
Crime and justice No
Dental No
Digestive system No
Ear, nose and throat No
Education No
Endocrine and metabolic disorders No
Eye disorders No
General interest Yes
Genetics No
Health inequalities/health equity No
Infections and infestations No
International development No
Mental health and behavioural conditions No
Musculoskeletal No
Neurological No
Nursing No
Obstetrics and gynaecology No
Oral health No
Palliative care No
Perioperative care No
Physiotherapy No
Pregnancy and childbirth No
Public health (including social determinants of health) No

Rehabilitation No
Respiratory disorders No
Service delivery No
Skin disorders No
Social care No
Surgery No
Tropical Medicine No
Urological No
Wounds, injuries and accidents No
Violence and abuse No

31. Language

Select each language individually to add it to the list below, use the bin icon to remove any added in error.

English

There is not an English language summary

32. Country

Select the country in which the review is being carried out from the drop down list. For multi-national collaborations select all the countries involved.

Scotland

33. Other registration details

Give the name of any organisation where the systematic review title or protocol is registered (such as with The Campbell Collaboration, or The Joanna Briggs Institute) together with any unique identification number assigned. (N.B. Registration details for Cochrane protocols will be automatically entered). If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here. If none, leave blank.

34. Reference and/or URL for published protocol

Give the citation and link for the published protocol, if there is one Give the link to the published protocol. Alternatively, upload your published protocol to CRD in pdf format. Please note that by doing so you are consenting to the file being made publicly accessible.

No I do not make this file publicly available until the review is complete

Please note that the information required in the PROSPERO registration form must be completed in full even if access to a protocol is given.

35. Dissemination plans

Give brief details of plans for communicating essential messages from the review to the appropriate audiences.

The essential messages from the current systematic review will published in an

academic journal which is deemed most relevant to appropriate audiences. It will therefore be written in accordance with guidelines for publication in the British Journal of Health Psychology and in accordance with the PRISMA statement.

Do you intend to publish the review on completion?
Yes

36. Keywords
Give words or phrases that best describe the review. Separate keywords with a semicolon or new line. Keywords will help users find the review in the Register (the words do not appear in the public record but are included in searches). Be as specific and precise as possible. Avoid acronyms and abbreviations unless these are in wide use.

Diabetes, Health Locus of Control (HLoC); Self-management; Adherence

37. Details of any existing review of the same topic by the same authors
Give details of earlier versions of the systematic review if an update of an existing review is being registered, including full bibliographic reference if possible.

Not applicable

38. Current review status
Review status should be updated when the review is completed and when it is published. For new registrations the review must be Ongoing. Please provide anticipated publication date Review.

Ongoing

39. Any additional information
Provide any other information the review team feel is relevant to the registration of the review.

The start date of the review was listed as 04.03.19 as this is the earliest record I have (by means of meeting minutes) of when the initial conversations with the research team surrounding the review topic took place. However, due to other work commitments and changes to the research question, the review (preliminary searches) started more recently. I have therefore amended the date to two weeks ago from today's date, however, should the Prospero team feel it would be more appropriate to list the date as when the initial conversations took place, I can revert this amendment.

40. Details of final report/publication(s)
This field should be left empty until details of the completed review are available. Give the link to the published review.

Appendix III. PRISMA Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	11
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	14
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	15/16
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	15/16
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	17 & Appendix II on page
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	29
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	30
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	29
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	32
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	39
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	39
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	39
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	43
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	43

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	44
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	32
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	34
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	39
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	46
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	46
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	46
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	46
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	47
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	49
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	N/A

Appendix IV. Ovid Search Terms and N Records Identified

	Search Term	*N* Records Identified
1	diabet*	1812465
2	HbA1c	105445
3	self*manage*	1761
4	self*directed	155
5	intervention	1778272
6	treatment	12002516
7	(health) locus of control	4495
8	(H)LoC	225
9	(diabetes) locus of control	46
10	(D)LoC	28
11	adher*	5484410
11	engage*	507832
13	drop*out	27105
14	attrition	36528
15	compliance	510213
16	comply	29143
17	discontinuation	141875
18	1 OR 2	1820553
19	3 OR 4 OR 5 OR 6	13111617
20	7 OR 8 OR 9 OR 10	4577
21	11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17	1642759
22	18 AND 19 AND 20 AND 21	56
23	Deduplicate	**42***

*Final *N* records screened for eligibility

Appendix V. Adapted AXIS Tool for Critically Evaluating Cross-Sectional Studies

			Quality Assessment Criteria
1	**Introduction**	**A**	Were the aims / objectives of the study clear?
2	**Methodology**	**B**	Was the study design appropriate for the stated aim(s)?
		C	Was the sample size justified?
		D	Was the target population clearly defined?
		E	Was the sample frame taken from an appropriate population base so that it closely represented the target population under investigation?
		F	Was the selection process likely to select participants that were representative of the target population?
		G	Were measures undertaken to address and categorise non-responders?
		H	Were the independent and dependent variables measured appropriate to the aims of the study?
		I	Were the independent and dependent variables measured correctly using measurements that had been trialled, piloted or published previously?
		J	Is it clear what was used to determined statistical significance and / or precision estimates? (e.g. *p* values, CIs)
		K	Were the methods (including statistical methods) sufficiently described to enable them to be repeated?
3	**Results**	**L**	Were the basic data adequately described?
		M	Does the response rate raise concerns about non-response bias?
		N	If appropriate, was information about non-responders described?
		O	Were the results internally consistent?
		P	Were the results for the analyses described in the methods, presented?
4	**Discussion**	**Q**	Were the authors' discussions and conclusions justified by the results?
		R	Were the limitations of the study discussed?
5	**Other**	**S**	Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?
		T	Was ethical approval or consent of participants attained?

Appendix VI. List of Excluded Studies

Excluded following title screening (*n* = 11):

Brownlee-Duffeck, M., Peterson, L., Simonds, J., Goldstein, D., Kilo, C., & Hoette, S. (1987). The Role of Health Beliefs in the Regimen Adherence and Metabolic Control of Adolescents and Adults with Diabetes Mellitus. *Journal of Consulting and Clinical Psychology, 55*(2), 139-144.

Epstein, F., Kale, P., Trammell, J., Stevenson, J., Polland E., Weisshaar D., Barbosa, A. … & Cosci, F. (2013). The locus of control, when left to chance, has a negative impact on immunosuppressant therapy adherence. *Psychotherapy and Psychosomatics, 82,* 28-29. https://doi.org/10.1159/000354142

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THESIS

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Understanding Uptake, Adherence, and Outcome in Computerised Cognitive Behavioural Therapy (cCBT): Evidence from Sociodemographic, Clinical, and Healthcare-Belief Perspectives

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Chapter 2. Understanding Uptake, Adherence, and Outcome in Computerised Cognitive Behavioural Therapy (cCBT): Evidence from Sociodemographic, Clinical, and Healthcare-Belief Perspectives

Understanding Uptake, Adherence, and Outcome in Computerised Cognitive Behavioural Therapy (cCBT): Evidence from Sociodemographic, Clinical, and Healthcare-Belief Perspectives

Abstract

Objectives: Little is known about the role of Health Locus of Control (HLoC) or attitudes towards eHealth (AteH) in the context of internet-based psychological interventions. The current study aims to explore the predictive value of these healthcare belief-related factors, along with other potentially important sociodemographic and clinical factors, to develop a better understanding of who might respond to and benefit from computerised Cognitive Behavioural Therapy (cCBT). ***Design:*** The study followed a longitudinal design with three time-points. ***Methods:*** Data collected as part of the Scottish national cCBT project from *N*=27990 patients referred to receive cCBT as an intervention for mild to moderate depression and/or anxiety across 14 Scottish NHS health boards. Of the 27900 patients, *n*=2130 opted to complete the optional measures of HLoC and AteH and formed the main study sample. Participants included ***Results:*** Neither of the healthcare belief-related factors were found to significantly predict uptake in cCBT services, however both HLoC and AteH predicted higher adherence to cCBT, and various HLoC domains significantly predicted magnitude of clinical changes across treatment. Other significant sociodemographic and clinical predictors of adherence and reductions were found and discussed. ***Discussion:*** The current study demonstrates interesting insights into the sociodemographic, clinical, and psychological factors predicting response to cCBT and may help inform clinicians in making referrals to this mode of therapy.

Key Words: Health Locus of Control (HLoC); computerised Cognitive Behavioural Therapy (cCBT); Uptake; Adherence; Outcome

1. Introduction

1.1 Computerised Cognitive Behavioural Therapy

Internet interventions are increasingly offered across healthcare services worldwide as part of an effort to increase access to psychological therapies (Chen *et al*., 2020; Christensen &

Griffiths, 2002; Doherty, Coyle & Sharry, 2012; Vis *et al*., 2015). Computerised Cognitive Behavioural Therapy (cCBT) offers a mechanism for reaching wide and disperse areas of the population (Vallury, Jones & Oosterbroek, 2015; Eysenbach, Mindlis, Mclellan & Vallury, 2015), thus increasing capacity to deliver services more widely. This is valuable to NHS Scotland which serves remote areas such as the Highlands and Islands. Clinical psychology services in Scotland follow a 'stepped-care' model for delivering care, meaning that patients are offered the least intrusive and most effective intervention appropriate for their presenting symptoms (National Institute for Health and Care Excellence [NICE], 2006). CCBT fits within step two of this model as a low-intensity intervention for mild to moderate presentations and offers a more flexible option to receive CBT than attending clinic appointments (Foroushani, Schneider & Assareh, 2011). The Scottish Government (2017) named the national implementation of cCBT as a key objective in the Mental Health Strategy, with the aim of increasing accessibility to psychological therapies. This objective is supported by NICE and the Scottish Intercollegiate Guidelines Network (SIGN) (NICE, 2006; SIGN, 2010), and the 'Beating the Blues' (BtB) programme is named specifically within the guidelines as an appropriate evidence-based intervention for those experiencing mild to moderate symptoms of depression and anxiety. The BtB programme consists of eight one-hour text-based self-help sessions which include elements of psychoeducation, behavioural activation, and cognitive work, with printable worksheets for patients to download and keep for future reference.

Despite BtB being a relatively new treatment modality, there is a growing amount of evidence to support its clinical efficacy. Research demonstrates a range of reductions, including significant reductions in self-reported psychological distress (Learmonth & Rai, 2008), depression (Proudfoot *et al*., 2003; Proudfoot *et al*., 2004; Omrod, Kennedy, Scott, & Cavanagh, 2010), and anxiety (Proudfoot *et al*., 2003). Such improvements have been identified across a range of services including primary care (Proudfoot *et al*., 2004), secondary care (Learmonth & Rai, 2008), and specialist care services (Learmonth, Trosh, Rai, Sewell, & Cavanagh, 2008), as well as in treating those experiencing depression with physical comorbidities such as multiple sclerosis (Cooper *et al*., 2011). In contrast to the above listed support for the clinical efficacy of BtB, one study by Gilbody *et al*. (2015) concluded that BtB provided no greater benefit than GP 'treatment as usual' (TAU; control condition) alone in reducing symptoms of depression. However, these findings have been criticised due to several potentially confounding factors (Cunningham, 2015; Christensen, Cuijper & Proudfoot, 2015; Jones, 2015). For example, GP TAU included the use of antidepressants medication (ADM),

as well as counselling, psychological, and secondary care mental health services. Furthermore, 19% of those receiving GP TAU had access to psychological internet interventions (including cCBT programmes), therefore the extent to which the treatment condition can be distinguished from the control condition is questionable.

Although the clinical efficacy of cCBT programmes is overall well supported, one of the main criticisms of cCBT is that it is claimed to have poor uptake and adherence (Melville, Casey & Kavanagh, 2010; Donkin *et al*., 2011; Titov *et al*., 2013). A systematic review of the relevant literature by Beatty and Binnion (2016) analysed data from 36 studies investigating predictors of, and reasons for, adherence to online psychological interventions. The review found several predictors of adherence to internet interventions; however, the results were either too contradictory or preliminary to draw conclusions, and the reviewers state that further research is needed to firmly establish predictors of engagement with online psychological interventions. Notwithstanding this, Beatty and Binnion highlight the following factors as predicting higher adherence to online psychological interventions: being female, higher expectancies of treatment, having a personalised intervention, and having enough perceived time to complete the treatment. Conflicting evidence regarding the predictive value of age and pre-treatment symptom severity was identified. A recent study by Chen *et al.* (2020) investigated predictors of adherence to and treatment outcomes of internet-based CBT (iCBT) as an intervention for social anxiety disorder (SAD) in China. Chen *et al.* found that having a diagnosis of SAD significantly predicted adherence to iCBT, compared to a control group of those with sub-diagnostic symptoms of social anxiety, indicating that greater severity of symptomology may play a part in likelihood of adhering to psychological therapy via the internet. Despite these findings, the authors underline the need for further qualitative research into the factors involved in adherence, highlighting specifically the importance of understanding patient's motivations for adhering to iCBT.

There are also gaps in the literature regarding which factors might predict the magnitude of clinical response to cCBT, however a small number of studies have made progress in exploring this question. Firstly, Spek, Nyklíček, Cuijpers and Pop (2007) investigated personality traits as potential predictors of clinical outcome (reductions in self-reported depression) across cCBT and group CBT treatments. Spek *et al*. found that greater changes in depression were predicted by higher altruism traits and lower neuroticism traits, as well as higher baseline Beck Depression Inventory (BDI; Beck, 1961) scores and being female. A second study by Esther

de Graaf, Hollon and Huibers (2010) investigated several pre-treatment and short-term improvement variables as potential moderators/predictors of outcome at 12-months follow-up following cCBT. The study followed a randomised controlled trial (RCT) design exploring perceived quality of life and dysfunctional attitudes as potential key predictors of improvements in self-reported depression between pre- and post-treatment. Esther de Graaf, Hollon and Huibers found that those with extreme (positive) responding (greater perceived quality of life and less dysfunctional attitudes) reported greater reductions in symptoms following the course of cCBT. A third study by Høifødt *et al.* (2015) investigated predictors of response to cCBT (with high-intensity therapist-guidance) as measured by changes in self-reported depression, and the rate of these changes as measured by how quickly reductions in scores emerged. Høifødt *et al.* (2015) found that higher numbers of depressive episodes prior to treatment, higher ratings of life satisfaction, and cohabiting or being married predicted greater chances of positive treatment response. A fourth study by El Alaoui *et al*. (2016) evaluated a large battery of potential predictor variables (38 in total) against their individual ability to predict both rate of clinical improvements and post-treatment outcomes. The study followed a cohort design and recruited adults receiving 'routine internet-based psychiatric care', which involved three months of access to cCBT guided remotely by a qualified Psychologist who would provide regular feedback. The 38 predictor variables were divided into six main categories including clinical characteristics (11 variables), sociodemographic characteristics (6 variables), family history of mental illness (10 variables), comorbidity of illness (9 variables), and two treatment-related factors (adherence and treatment credibility). El Alaoui *et al*. found that stronger adherence to treatment, greater perceived treatment credibility, more severe pre-treatment depression, and working full-time predicted greater improvements in depression symptoms. A fifth study by Cientanni *et al.* (2019) conducted a study across five Scottish NHS health boards to investigate predictors of magnitude of clinical change across cCBT. Cientanni *et al.* found that psychological distress reduced significantly in those who completed the course of treatment, and that the magnitude of these clinical improvements were predicted by perceived social connectedness (greater number of social group identifications), more severe pre-treatment psychological distress, taking ADM concurrently with cCBT, and living in a lesser state of socioeconomic deprivation. Finally, and most recently, Chen *et al.* (2020) found evidence that greater reductions in SAD symptom severity were predicted by being female.

Despite the limited amount of research into predictors of uptake, adherence and outcome in cCBT, some interesting patterns are starting to emerge. The main limiting factor of this growing evidence-base is the restricted exploration of other potentially important theoretical underpinnings which may help to explain response to cCBT. The following sections offer a critical review of the factors which theoretical, clinical and sociodemographic factors may help to explain uptake, adherence and clinical outcomes in cCBT.

1.2 Health Locus of Control

The theory of health locus of control (HLoC) offers an explanation to understand health-related decision making. The theory is based on principles of social learning theory (SLT; Rotter, 1954), which describe how behaviours are a function of both an expectancy that the behaviour will result in a particular outcome and the value of the expected outcome. Therefore, if SLT were to be applied to engagement and potential clinical gains in cCBT, 'adherence' would be the behaviour driven by both the expectancy that they are likely to gain clinical benefits from engaging with cCBT and the perceived value of such clinical benefits. Wallston (1991) built on SLT by focusing on the expectancy element of SLT theory to create the theory of HLoC. HLoC theorises that expectancies are placed on the degree of control one has over ones' health outcomes. In other words, the theory of HLoC suggests that there is variation in the perceived 'location' of control over health outcomes. The location of perceived of control is polarised by two extremes: internal and external locus of control. Those with a strong internal HLoC (iHLoC) believe that they themselves have firm control over their own health outcomes. Whereas those with a strong external HLoC (eHLoC) believe that they have little control over their own health outcomes. Within eHLoC, Wallston, Stein and Smith (1994) also theorised that there are various locations in which people might identify the source of control over their health outcomes. These include within other people ('others' HLoC) and in doctors ('doctors' HLoC). Similarly, Wallson, Stein and Smith hypothesised that some might believe that control over their health outcomes is not located within themselves or other people, but that chance or luck may play a role in determining the condition of their health ('chance' HLoC). Kirscht (1972) explains the important difference between motivation to control one's health and HLoC, noting that whilst they might both predict health behaviours, they are two separate constructs.

Regarding the influence of HLoC on uptake, adherence and treatment outcome, the current literature focuses almost exclusively on physical health conditions, and its relevance to cCBT treatment response remains unknown, as no research to date has been conducted in this area.

However, if the relationship between HLoC and response to other types of health interventions is presumed to be similar to response to cCBT, then the following evidence could be considered. West, Borg Theuma and Cordina (2018) investigated the relationship between HLoC and medication adherence and wastage in chronic health conditions (asthma, cardiovascular problems or diabetes). The study found that weaker 'chance' HLoC beliefs significantly predicted greater adherence to medication regimens. Regarding adherence to mental health medication adherence, De las Cuevas, Peñate and Sanz (2014) conducted a cross-sectional study across *N*=119 psychiatric outpatients to investigate the role of HLoC, perceived self-efficacy, and psychological reactance in adherence to their prescribed ADM treatment. The study found that only the 'doctors' HLoC subscale significantly predicted adherence to treatment, with the authors suggesting that this finding may be related to the doctors (psychiatrists) playing a significant role in determining the required treatment plan (by prescribing ADM). It is possible that determining whether to start cCBT might require a more active or collaborative role from the patient (Kaltenthaler & Cavanagh, 2006).

1.3 Attitudes towards eHealth

Attitudes towards eHealth (AteH) may also be an important factor in driving uptake, adherence, and outcome. From a theoretical perspective, SLT would hypothesise that people are more likely to engage with a service if they believe that the service is valuable or appropriate for meeting their specific needs. However, research into attitudes towards using eHealth in a clinical psychology population is limited. A recent meta-review summarised the literature regarding patient acceptability of cCBT as an intervention (Rost *et al.,* 2017). Rost *et al.* reviewed twelve systematic reviews on the acceptability of cCBT and identified several key factors important to patients when engaging with cCBT services, with acceptability of the intervention being consistently predictive of adherence. Similarly, El Alaoui *et al.* (2016) found that those who rated the credibility of the intervention more positively made greater gains from completing the intervention as measured by self-reported depression scores. However, none of the studies reviewed by Rost *et al.* examined attitudes towards eHealth as a mechanism for accessing healthcare; rather they focused on the acceptability of specific programmes. No literature exists to explain the relationship between attitudes towards eHealth and uptake, adherence and outcome in cCBT. By assessing AteH, it is hoped that more will be learned about peoples' attitudes towards using the internet as a part of their healthcare, which is of relevance to those accessing cCBT services. Hence, it is important to fill the gap in the literature

examining the relationship between attitudes toward eHealth and engagement with psychological eHealth interventions such as cCBT.

1.4 Clinical Factors

There are several clinical factors which have been found to influence uptake, adherence, and outcome. Severity of depression prior to treatment is an important variable in relation to both engagement and outcome in psychological interventions. Studies have shown that those who are more severely depressed are less likely to engage with computerised psychological interventions (Knowles *et al*., 2015). This may be related to one of the core symptoms of depression being marked a lack of motivation (APA, 2013; World Health Organisation [WHO], 1992). From a theoretical perspective, Clark and Beck (2010) underline why such cognitive elements are crucial in depression, explaining how depression can decrease motivation to engage with tasks, one of which may be treatment. Grahek, Shenhav, Musslick, Krebs, & Koster, (2019) build on this theory to present a model suggesting that motivation is inherent in cognitive control, which is essential in completing emotionally demanding tasks (such as therapy). Similarly, other studies consistently demonstrate the impact of low motivation on cognition more generally (Moritz *et al*., 2017), which again could influence uptake and engagement in a cognitively demanding task such as self-directed cCBT. Given the theorised importance of depression severity on engagement, it is important to include this as a variable in a model testing factors which influence uptake and engagement.

Evidence is more mixed regarding the relevance of severity of depression and the magnitude of clinical gains following low-intensity psychological interventions such as cCBT. In a comprehensive meta-analysis examining the influence of pre-treatment severity of depression on outcome in those receiving low intensity interventions as a treatment for depression (*N*=2470), Bower *et al.* (2013) found that those who were more severely depressed prior to treatment benefited from larger treatment effects than those who were less severely depressed. Similarly, other studies have identified that those with more severe symptoms pre-treatment make greater improvements over the course of cCBT (Spek, Nyklíček, Cuijpers & Pop, 2007; El Alaoui *et al*., 2016; Cientanni *et al*., 2019). Of course, these effects are likely mediated by adherence to treatment, if indeed the treatment is effective in supporting individuals to resolve their symptoms, as demonstrated by El Alaoui *et al*.'s finding that high adherence to treatment coupled with greater severity of pre-treatment depression predicted greater reductions in self-reported depression over the course of treatment. Another possible reason as to why pre-

treatment severity of distress may be related to a greater magnitude in clinical outcomes post-treatment could simply be that there is more room for symptom improvement if the baseline is high. However, some previous research also found no significant interaction between pre-treatment depression severity and the therapeutic effects of cCBT (Proudfoot *et al.,* 2003) or between pre-treatment depression and treatment response as measured by changes in BDI scores (Høifødt *et al*., 2015).

The use of ADM may also predict the likelihood of starting, adhering to, and gain clinical benefits from using cCBT because ADM use may, as intended, reduce the severity of depressive symptoms (APA, 2000; Fournier *et al*., 2010), and may therefore lead to greater reductions in psychological distress over the course of cCBT compared to using cCBT as a stand-alone intervention. The theories surrounding the underpinning mechanisms of ADM are wide ranging and in some cases are dependent on the type of drug in question, with some studies concluding that it is difficult to establish how exactly various drugs improve mood. However, Pringle, Browning, Cowen and Harmer (2011) present a cognitive neuropsychological model of ADM action, suggesting that improvements in depressive symptoms may be accounted for by changes in emotional processing. Specifically, Pringle, Browning, Cowen and Harmer theorise that ADM may contribute to shifting negative biases inherent in depressive presentations, which in turn creates a more positive perceived environment for the individual to gain new and positive emotional experiences. In reducing the severity of depressive symptoms, ADM use may contribute to improving motivation and cognitive control as outlined above, and therefore from a theoretical perspective this is an important variable to include in the current model. Indeed, this concept has been supported by Cientanni *et al*. (2019) within a Scottish primary care sample, in that taking ADM concurrently with cCBT predicted greater reductions in psychological distress between pre- and post-treatment. In contrast to this hypothesis, those with a history of using psychotropic medication completing cCBT have been found to make slower improvement and have higher post-treatment self-reported depression scores (El Alaoui *et al*., 2016). Notwithstanding these findings, Proudfoot *et al.* (2004) demonstrated that the effects of BtB did not interact with concurrent ADM use, indicating that BtB can provide clinical benefits with or without concurrent ADM use; therefore, the impact of ADM use in those completing cCBT remains somewhat unclear. From a theoretical perspective, it is crucial to include such clinical considerations within a model testing factors related to uptake, engagement and outcome given

the above listed previous studies have demonstrated the importance of such variables in this context.

1.5 Sociodemographic Factors

Finally, there are several demographic factors to consider when investigating uptake, adherence and outcome in cCBT. Most notably, sociodemographic theory is a key area of research in understanding health behaviours. Nölke, Mensing, Krämer and Hornberg (2015) investigated the sociodemographic and health-care-related characteristics of online health information seeking behaviour. The study discussed the theoretical importance of investigating such factors within the developing field of online health interventions, and found that those from 'middle' or 'upper' social classes were more likely to use the internet to seek health information than those from 'lower' classes. Nölke, Mensing, Krämer and Hornberg theorised that this difference may be related to access to required technologies, highlighting again social inequalities in health behaviours, and stressing the need for a multifactorial framework for understanding 'Health Information Seeking Behaviour (HISB). Arguably there are similarities between HISB and uptake / engagement with cCBT as a mode of therapy.

With regards to gender differences in psychological therapy in general, studies have consistently demonstrated that men can struggle to seek support for mental health concerns, and engage with certain aspects of face-to-face therapy (Seidler, Rice, Ogrodniczuk, Oliffe, & Dhillon, 2018). Theories behind the reasons for these findings have centred on restrictive elements that constitute the construct of 'masculinity' which conflict with emotional vulnerability and open communication required by psychological therapy, including strength and stoicism (Seidler *et al*., 2016; Vogel & Heath, 2016). However, such theories have been challenged by the idea that men's difficulties to engage with therapy is driven by limitations of therapists and services, such as inadequate training in sensitivities surrounding gender differences (Mellinger & Liu, 2006), biases against, or indeed towards, masculinity (Owen, Wong, & Rodolfa, 2009), and structural barriers such as service environments (Seidler *et al.,* 2017). With regards to computerised therapies, it is possible that the effect of the theories surrounding masculinity described above may be removed by the modality of the therapy. For example, it is possible that removing the therapist from the treatment and replacing the therapist with self-directed exercises may remove the drive to conceal emotional vulnerability and free men to communicate their emotions more openly, as well as removing any potential clinician biases and structural barriers. However, limited data has found that being female significantly

predicts better outcomes in internet-based CBT as measured by differences in BDI scores from pre- to post-treatment (Spek *et al.*, 2007).

Regarding age, differences have been found in engagement and outcome in cCBT across age groups. A meta-analysis by Grist and Cavanagh (2013) revealed that those who are older are more likely to have poorer outcomes from cCBT. However, a review by Crabb *et al*. (2012) demonstrated that older adults actually engage better than, or at least as well as, younger adults. Musiat, Goldstone and Tarrier (2014) found that age was significantly (but weakly) negatively correlated with computer literacy, which may help to explain Grist and Cavanagh's findings. From a theoretical perspective, it has been postulated that factors related to age, including generational beliefs and stigma surrounding mental health, may serve as a barrier for older adults accessing face-to-face psychological therapy (Cole, McCusker, Sewitch, Ciampi, & Dyachenko, 2008). Therefore, it is possible that cCBT offers a way to eliminate said barriers by removing the therapist interaction and necessity to travel to clinic appointments, therefore it is important to explore the effects of age within an integrative model to understand uptake, engagement and outcome in cCBT.

Higher educational attainment has been found to predict greater outcomes from cCBT, with the authors suggesting that this may be because cCBT as an intervention relies on literacy and self-directed learning (Spek, *et al*., 2007). From a theoretical perspective, it is therefore possible that the cognitive demands of self-directed psychological therapy may be easier to meet for those with higher educational attainment than those with lower educational attainment, thus educational attainment is an important variable to include when exploring an integrative model to explain uptake, engagement and outcome in cCBT.

El Alaoui *et al*. (2016) also found that working full-time predicted greater reductions in self-reported depression over the course of treatment, however offered no clear explanation for this. It is possible that unemployment serves as an additional source of stress for the individual (financial worries), which may exacerbate existing symptoms of depression (Kessler, Turner & House, 1987). Additionally, full-time employment may serve to reduce depressive symptoms by acting as a means of behavioural activation (Murphy & Athanasou, 1999) linking to behavioural theories of depression (Ferster, 1973), or by providing the individual with a sense of role and purpose (Musick & Wilson, 2003). Similarly, it could be theorised that marital status may also serve as a protective factor in the treatment of depression (Kessler & Essex,

1982), with the social support derived from marriage serving as a protective factor (Barrett, 2000). However, research into the links between marital status and engagement and outcome in cCBT is non-existent, despite marital status being considered an important sociodemographic in health-related research.

In conclusion, the above listed sociodemographic factors constitute as essential variables to consider as part of an integrative model for understanding uptake, engagement and adherence to cCBT.

1.6 Rationale & Aims

While the above studies provide valuable insights into several clinically relevant factors associated with uptake, adherence, and clinical outcome, no study to date has considered an integrative model to evaluate the importance of HLoC and AteH together with key sociodemographic and clinical variables as potential predictors of these treatment-related factors in cCBT. Additionally, despite the existing literature having addressed and explored a number of important factors related to cCBT response, several limitations and inconsistencies remain. These include failing to control for the potential influence of education (Høifødt *et al.,*2015), and of ADM use (Spek *et al*., 2008; Esther de Graaf, Hollon, & Huibers, 2010; Høifødt *et al.,*2015), or measuring history of psychotropic medication use as opposed to concurrent ADM use (El Alaoui *et al*., 2016), measuring number of previous episodes of depression as opposed to chronicity of current problem (Spek *et al*., 2008; Høifødt *et al.,*2015), and using a cCBT intervention which involved a high degree of therapist guidance; therefore making it difficult to distinguish which factors may predict treatment outcome through cCBT alone without therapist input (Høifødt *et al.,*2015).

Understanding which health belief-related and attitudinal factors may predict cCBT treatment response, along with potentially important clinical and sociodemographic factors, is fundamental in enabling clinicians to make well-informed and appropriate clinical judgements regarding referrals to cCBT services. This forms the core aims of, and rationale for, the current study.

1.7 Hypotheses and Theoretical Model

Based on the existing literature in related fields, it is hypothesised that HLoC beliefs and more positive AteH will significantly predict greater uptake (likelihood of starting treatment), higher

adherence (number of sessions completed) and greater clinical changes (magnitude of symptom reductions). Regarding sociodemographic and clinical factors, based on previous literature, it is hypothesised that greater uptake, adherence and clinical response will be significantly predicted by more severe pre-treatment psychological distress, taking ADM concurrently, being employed, being female, and having a higher educational attainment. The above hypotheses form an integrative theoretical model which holistically accounts for the various individual factors which likely influence uptake, engagement and outcome.

2. Method

2.1 Participants and Procedure

Participants included patients referred by a clinician to receive cCBT via the BtB programme across all 14 Scottish NHS health boards over a 21-month period between July 2017 and March 2019. Referral criteria to the BtB programme included a suspected diagnosis of mild to moderate depression and/or anxiety (as determined by the referring clinician), >16 years of age, must not have any other significant psychological morbidity, and must not be actively suicidal.

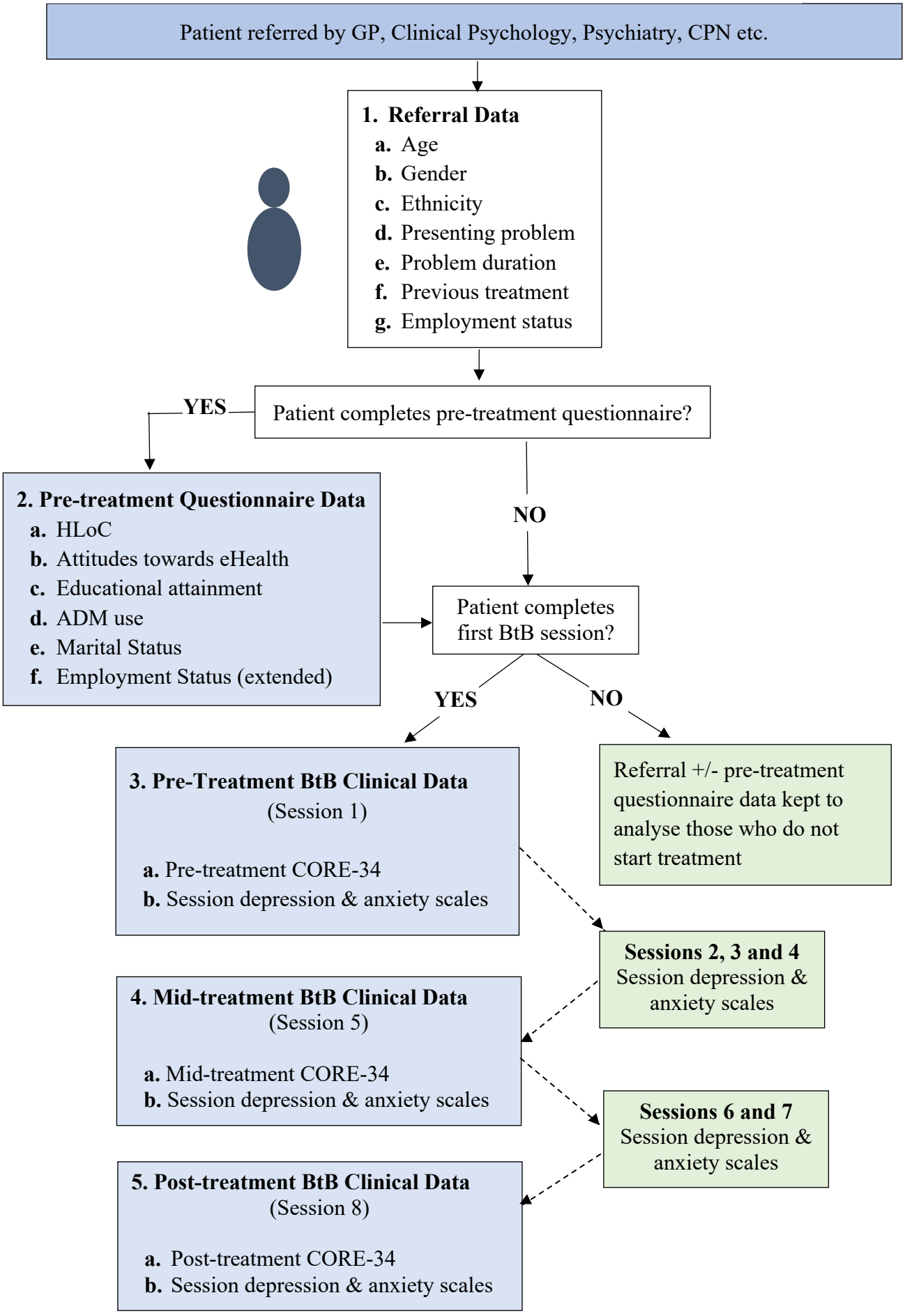
A designated local BtB coordinator contacted all referred patients to facilitate access to the BtB system and to address any queries. All patients were provided with the name and contact number of their local BtB coordinator should they have any difficulty with the treatment thereafter. Routine contact with the BtB coordinator varied across health boards, with some providing telephone support when required, to others offering an email or text message at specific points during treatment to offer encouragement and support.

Clinical, sociodemographic, and theoretical data were collected digitally via three sources at five main time-points across treatment. The three data sources include referral, pre-treatment questionnaire, and BtB programme information. It is possible for patients to drop out of treatment at any point in the process, from referral up to the final session of BtB. The pre-treatment questionnaire was optional; therefore, patients were able to progress through the BtB programme without having completed it. A diagram to show the pathway of data collection across the various time-points is provided in figure 1.

Ethical approval to use the data collected as part of the cCBT service for the purpose of conducting the current study was sought from and approved by the University of Edinburgh

Research Ethics Committee (REC; Ref: CLIN724, appendix V) and the Public Benefit and Privacy Panel (PBPP) for Health and Social Care (Ref: 192-0057, appendix IV).

Figure 1. *A diagram to show the pathway of data collection across time-points*



2.2 Referral Measures

Clinical and sociodemographic data concerning patient's age (years), gender (male/female), presenting problem (depression and/or anxiety, or other), ethnicity, problem duration, previous treatment, and employment status were collected by the BtB programme on referral to the programme.

2.3 Pre-Treatment Questionnaire Measures

The pre-treatment questionnaire mainly consisted of the theoretical measures (HLoC and attitudes towards eHealth), however also included additional sociodemographic measures of educational attainment, marital status, ADM use, and an extended question regarding employment status. The pre-treatment questionnaire was administered digitally via SurveyMonkey© on referral to the BtB service. Participants were sent an online link containing a unique patient identifier code to ensure anonymity of responses. Questionnaire responses were then later linked to anonymised referral and BtB clinical data using this unique code.

2.3.1 HLoC

Form C of the Multidimensional Health Locus of Control Scale (MHLC; Wallston, Strudler-Wallston & DeVellis, 1978) was used to assess HLoC. The MHLC form C is designed to measure HLoC related to a specific condition (Luszcynska & Schwarzer, 2005). In the context of the current study, the specific condition includes symptoms of depression and/or anxiety. The MHLC form C consists of 18 items in the form of statements. The extent to which participants agree or disagree with each statement can be indicated using a 6-point Likert scale of 'strongly agree', 'moderately agree', 'slightly agree', 'slightly disagree', 'moderately disagree', or 'strongly disagree'. The MHLC form C items are displayed in table 1.

Table 1. *MHLC Form C Items*

Item	Statement
1	If my condition worsens it is my own behaviour which determines how soon I will feel better again
2	As to my condition what will be will be
3	If I see my doctor regularly, I am less likely to have problems with my condition
4	Most things that affect my condition happen to me by chance
5	Whenever my condition worsens I should consult a medically trained professional
6	I am directly responsible for my condition getting better or worse
7	Other people play a big role in whether my condition improves or stays the same
8	Whatever goes wrong with my condition is my own fault
9	Luck plays a big part in determining how my condition improves
10	In order for my condition to improve, it is up to other people to see that the right things happen
11	Whatever improvement occurs with my condition is largely a matter of good fortune
12	The main thing which affects my condition is what I myself do
13	I deserve the credit when my condition improves and the blame when it gets worse
14	Following doctor's orders to the letter is the best way to keep my condition from getting worse
15	If my condition worsens it's a matter of fate
16	If I am lucky my condition will get better
17	If my condition takes a turn for the worse, it is because I have not been taking proper care of myself
18	The type of help I receive from other people determines how soon my condition improves

Items representing each subscale described by Wallston, Stein and Smith (1994) are displayed in table 2.

Table 2. *MHLC Form C subscales and corresponding items*

MHLC Form C Subscale	Items
Internal HLoC	1,6, 8, 12, 13, 17
Chance HLoC	2, 4, 9, 11, 15, 16
Doctors HLoC	3, 5, 14
Others HLoC	7, 10, 18

A scale validation study by Wallston, Stein and Smith (1994) found the MHLC form C to have a clean factor structure with factor loadings of >.7, good internal consistency (alpha >.70), and concurrent validity with significant correlations between .30 and .68 between subscales. However, it should be noted that the scale was validated within a population of those experiencing arthritis and chronic pain, therefore it cannot be claimed to be validated across all physical or mental health conditions.

2.3.2 AteH

AteH were measured using the eHealth Impact Questionnaire part one (eHIQ; Kelly, Jenkinson & Ziebland, 2013). Please see appendix VI for the eHIQ license agreement for the use of this measure. The eHIQ (parts 1 and 2) was developed by reviewing eHealth literature and conducting a qualitative analysis of interviews with *N*=99 patients to establish which factors are important to patients when accessing health-related information online (Kelly, Jenkinson & Ziebland, 2013). Five main themes were identified from this research: information, support, relationships with others, affecting behaviours, and experiencing health services. Items were formulated to address these key themes and were reviewed by an expert panel of clinicians and academics with eHealth experience.

The eHIQ part one consists of 11 items in the form of statements. Participants indicate the extent to which they agree or disagree with each statement using a 5-point Likert scale of 'strongly agree' (5), 'agree' (4), 'neither agree nor disagree' (3), 'disagree' (2), or 'strongly disagree' (1). Scoring therefore produces a possible maximum of 55 (strong belief in positive impact of using eHealth) and minimum of 11 (strong belief in negative impact of using eHealth). For the purpose of the analysis, eHIQ responses will be treated as a scale variable. The eHIQ items used are displayed in table 3.

Table 3. *eHIQ Items*

Item	Statement
1	The internet is a reliable resource to help me understand what a doctor tells me
2	The internet can help people know what it is like to live with a health problem
3	The internet can be useful to help people decide if their symptoms are important enough to go to see a doctor
4	I would use the internet if I needed help to make a decision about my health (for example, whether I should see a doctor, take medication or seek other types of treatment)
5	I would use the internet to check that the doctor is giving me appropriate advice
6	The internet is a good way of finding other people who are experiencing similar health problems
7	It can be helpful to see other people's health-related experiences on the internet
8	The internet is useful if you don't want to tell people around you (for example, your family or people at work) how you feel
9	It can be reassuring to know that I can access health-related websites at any time of the day or night
10	The internet is a good way of finding other people who are facing health-related decisions I may also face
11	Looking at health websites reassures me that I am not alone with my health concerns

Despite being a relatively new psychometric measure, the eHIQ has been validated in a small sample (N=170) consisting of people experiencing a range of health concerns, from chronic conditions to those intending to modify their health behaviours (Kelly, Ziebland & Jenkinson, 2015). Kelly, Ziebland and Jenkinson found that, following the removal of a factor with poor internal consistency (Cronbach's alpha = .59), all factors had a Cronbach's alpha level of >.77. The study also demonstrated good internal consistency between the two subscales (>.77). Pearson's r correlation coefficients revealed weak to moderate correlations between sub-scales (.35 to .52), suggesting that the scales are significantly related but sufficiently divergent. Test-retest reliability was also explored by asking participants to repeat the measure after a 2-week interval, with levels of agreement between tests ranging from .76 to .91 across all domains, suggesting good test-retest reliability.

2.3.3 ADM Use

To measure ADM use, participants were asked the following single-item self-report question: 'At the moment, do you take antidepressant medication, and if so for how long?' to which they were able to respond 'yes, for less than 1 month', 'yes, for less than 2 months', 'yes, for more than 2 months', or 'I do not currently take antidepressant medication'. For the purpose of the analysis, ADM use answers will be dichotomised to represent those taking and those not taking ADM.

2.3.4 Educational Attainment

Educational attainment was measured using the following single-item self-report question included in the pre-treatment questionnaire: 'What is the highest level of education you have received and completed?' to which participants could respond 'primary', 'secondary', 'higher and/or university', or 'other'. Educational attainment data were treated as ordinal data for the purpose of the analysis.

2.3.5 Marital Status

Marital status information was collected using the following single-item self-report question: 'Please select the option which best describes your current status' to which participants can respond 'single', 'in a relationship', 'cohabiting', 'civil partnership', 'married', or 'divorced'. Marital status data were treated as categorical data for the purpose of the analysis.

2.3.6 Employment Status

An extended question regarding employment status from the referral information was administered as part of the pre-treatment questionnaire using the following single-item self-report question: 'Please select the answer which best describes your current status' to which participants can respond 'employed – currently attending work', 'employed – currently taking sickness absence', 'full-time education – currently in attendance', 'full-time education – currently taking sickness absence', 'unemployed', or 'retired'. Employment status data were treated as categorical data for the purpose of the analysis.

2.4 BtB Clinical Measures

The BtB programme routinely administers clinical outcome measures in order to monitor patients' progress throughout treatment. These measures include

2.4.1 Psychological Distress

The Clinical Outcomes in Routine Evaluation Outcome Measure (CORE-OM; Evans *et al*., 2000) was used to assess severity of psychological distress at session 1 (pre-treatment), session 5 (mid-treatment), and session 8 (post-treatment). The CORE-OM is widely accepted and used in routine clinical practice (Gray & Mellor-Clark, 2007) and is a pan-diagnostic measure of psychological distress with four domains; 'wellbeing' (4 items), 'problem severity' (12 items), 'functioning' (12 items), and 'risk' (6 items). Each domain draws upon the opinions of clinicians regarding the most important elements of psychological wellbeing and health to measure (Mellor-Clark, Barkham, Connell & Evans, 1999). The 34 items are presented as statements to which participants are asked to rate how frequently, from 'not at all' to 'most or all of the time', they have felt the way the statement describes in the last week. The wellbeing domain measures the overall psychological wellbeing without being condition-specific, including statements such as "I have felt like crying". The functioning domain measures participants' level of social and general everyday functioning and includes statements such as "Talking to people has felt too much for me". The risk domain measures both risk to one's self (4 items) and to others (2 items) and includes items such as 'I have thought of hurting myself' and "I have been physically violent to others". Finally, the problem severity domain measures participants' severity of presenting symptoms, again without being condition-specific, by assessing different indicators of heightened psychological distress including physiological symptoms such as sleep.

Participants indicate a score between 0 and 3 per item, resulting in a total possible score range of 0 to 102. The total score is then divided by 34 to produce a total mean score. Internal consistency across all subscales has been reported to show Cronbach's alpha levels between >.75 and <.95, with an alpha level of .94 for all items in a clinical sample (Evans *et al*., 2002). Test-retest reliability of subscales has also been reported as high (between .87 and .91), with the exception of the risk subscale (.64) (Evans *et al*., 2002). Both individual domain and overall scores show excellent convergent validity against other self-report measures of symptom severity within clinical populations (CI ranges between .63 and .88 for all items) (Connell *et al*., 2007).

2.4.2 Depression and Anxiety

Two single-item self-report measures of depression and anxiety are administered each session. Participants are asked 'How (anxious or stressed) / (depressed) have you felt in the past week' on a Likert scale of 0 (not at all) to 8 (extremely anxious or stressed / depressed).

2.5 Uptake

Uptake across those referred to receive cCBT was determined by whether participants completed all clinical outcome measures administered during session 1 of BtB. A binary variable was computed based on this information to produce a yes/no answer to the question of uptake.

2.6 Adherence

Adherence to the BtB programme was measured by the number of sessions completed. The higher the number of sessions, the more strongly it is considered the participant adhered to the programme.

2.7 Clinical Outcome

Clinical outcomes were measured by assessing the clinical improvements (change scores) patients made across treatment. Change scores were calculated by assessing the difference between participants' pre-and mid-treatment, and pre- and post-treatment scores on all CORE-OM domains ('functioning', 'wellbeing', 'problem severity', 'risk', 'total' and 'total minus risk'). Greater change scores (CSs) indicate larger clinical improvements (reductions in psychological distress) whereas smaller positive CSs indicate modest clinical improvements. Only CORE-OM scores were used for the purpose of measuring clinical outcome (as opposed to also including the self-reported depression and anxiety scales) given that the CORE-OM is a validated measure, thus making the current study comparable with other research.

Preliminary research conducted in NHS Tayside using N=1873 patients revealed no significant difference between patients' clinical improvements as measured by the CORE-OM between sessions 5 and 8 of BtB, indicating a potential 'dosage' effect of 5 sessions to gain maximum clinical benefits of the programme (Battersby & Power, 2015). It is for this reason that predictors of change scores between sessions 1 and 5 (pre- to mid-treatment) as well as between sessions 1 and 8 (pre- to post-treatment) were investigated.

2.8 Statistical Analyses

An a priori analysis was conducted to establish the required sample size to answer the main research question: 'What value do sociodemographic, clinical and health belief factors have in predicting engagement (uptake and adherence) and outcome in cCBT services?' (two-tailed). The analysis was conducted using G* Power Analysis 3.1 software (Faul, Erdfelder, Buchner & Lang, 2009). The minimum sample size necessary to obtain adequate statistical power (1-β err. prob.=.95) to detect small effect sizes (F^2=.15), based on an alpha level of α=.05 and conducting a Multiple Linear Regression (MLR) with 10 predictor variables, was computed to be *N*=172. Data were analysed using Statistical (SPSS 25) software (IBM Corp, 2019).

Parametric tests were at first conducted to ensure that the parametric assumptions of normality, multicollinearity and homoscedasticity were not violated. A series of regression analyses were then conducted to test the effects of the main predictor variables (HLoC and attitudes towards eHealth) and eight secondary predictor variables (age, gender, educational attainment, employment status, marital status, ADM use, pre-treatment severity of psychological distress, and problem duration) on uptake, adherence and outcome respectively. These included a binary logistic regression (BLR) to investigate predictors of uptake (started BtB session 1, yes or no) and a series of MLR analyses to investigate predictors of adherence (number of BtB sessions completed) and outcome (clinical changes across treatment).

3. Results

3.1 Descriptive Statistics

A total of 27990 patients were referred to the BtB service during the inclusion period. Of those, *N*=21210 (75.8%) started the first session of BtB, and *n*=2130 (7.6%) also completed the pre-treatment questionnaire, forming the total study sample size. Of those referred, most were female (*n*=17,494; 62.5%) compared to male (*n*=10,496, 37.5%). The majority of participants were white British (*n*=25,233, 90.2%), or another white background (Irish *n*=289, 1%; white or any other white background *n*=1,641, 5.8%). A full report of participants ethnic background can be found in table 4.

Table 4. *Frequencies and percentages of ethnic background across participants*

Ethnicity	*n*	Percent (%)
Any other Ethnic group	157	.6
Asian	1	.0
Asian or Asian British - any other Asian background	60	.2
Asian or Asian British - Bangladeshi	22	.1
Asian or Asian British - Indian	88	.3
Asian or Asian British - Pakistani	112	.4
Black or African American	3	.0
Black or Black British - African	56	.2
Black or Black British - any other Black background	5	.0
Black or Black British - Caribbean	8	.0
Chinese	75	.3
Hispanic or Latino Origin	13	.0
Mixed - any other mixed background	94	.3
Mixed - White & Asian	80	.3
Mixed - White & Black African	32	.1
Mixed - White & Black Caribbean	19	.1
Native Hawaiian or other Pacific Islander	2	.0
White	369	1.3
White - any other Background	1272	4.5
White - British	25233	90.2
White - Irish	289	1.0
Total	27990	100.0

Most participants reported having some form of employment (*n*=16852, 60.2%) whereas a little over one fifth were unemployed (*n*=6257, 22.4%), and for some this question did not apply (*n*=4881, 17.4%).

The majority of participants reported experiencing mixed symptoms of both anxiety and depression (*n*=17003, 60.7%). Others reported experiencing either symptoms of anxiety (*n*=5985, 21.4%), depression (*n*=4099, 14.6%), or 'other' uncategorised symptomology (*n*=903, 3.2%). The duration of problems experienced by participants varied (less than 6

months *n*=2769, 9.9%; 6 months to a year *n*=4625, 16.5%; 1-3 years *n*=5,959, 21.3%; 3-5 years *n*=3793, 13.6%; 5-10 years *n*=4561, 16.3%; 10-20 years *n*=4164, 14.9%; 20-40 years *n*=1809, 6.5%; more than 40 years *n*=310, 1.1%). A little over half of participants had used drugs or medication to help manage their symptoms (*n*=14945, 53.4%), whereas *n*=8040 (28.7%) had received no prior intervention. The remaining participants had previously engaged with some form of psychological therapy, such as an anxiety management group (*n*=219, .8%), NHS counselling or psychotherapy (*n*=2438, 8.7%), private counselling or psychotherapy (*n*=1786, 6.4%), or inpatient therapy (*n*=39, .1%).

Mean self-rated depression and anxiety scores decreased across the course of therapy in those who started and adhered to the programme, from 4.60 in session one to 2.85 in session eight on the depression scale, and 5.44 in session one to 3.50 in session eight on the anxiety scale. The number of participants completing each session and the attrition rate (%) between sessions, along with the means and standard deviations of self-rated depression and anxiety scores at each session, and the psychological distress scores (CORE-OM Total) at sessions 1, 5 and 8 is reported in table 5.

Table 5. *Frequencies and percentages of participants completing each session, and the means and standard deviations of self-rated depression, anxiety and psychological distress scores*

Session Number	Depression		Anxiety		Psychological Distress	
	M	*SD*	*M*	*SD*	*M*	*SD*
Session 1 (*N*=21210, 100%)	4.60	2.12	5.44	1.73	1.96	.61
Session 2 (*n*=15613, 73.6%)	4.40	2.17	5.20	1.77	-	-
Session 3 (*n*=11150, 52.6%)	4.10	2.24	4.89	1.89	-	-
Session 4 (*n*=8911, 42.0%)	3.89	2.28	4.71	1.97	-	-
Session 5 (*n*=7107, 33.6%)	3.49	2.33	4.31	2.11	1.33	.67
Session 6 (*n*=5762, 27.2 %)	3.35	2.35	4.07	2.16	-	-
Session 7 (*n*=4952, 23.3 %)	3.21	2.36	3.89	2.20	-	-
Session 8 (*n*=4366, 20.6 %)	2.85	2.36	3.50	2.56	1.07	.67

Of the 27990 patients referred to the service during the inclusion period, *n*=2130 (7.6%) completed the optional pre-treatment questionnaire. Given that the remaining sociodemographic questions were raised as part of the pre-treatment questionnaire, it is only possible to report on data from these 2130 participants as follows.

Regarding educational attainment, most participants reported completing higher and/or university education (*n*=1275, 59.9%), with the remaining participants completing secondary (*n*=711, 33.4%), primary (*n*=17, .5%), or another unspecified form of education (*n*=127, 5.9%). Regarding marital status, participants were split almost equally by one third between reporting being married (*n*=742, 34.8%), single (*n*=615, 28.9%), or in a relationship (*n*=493, 23.2%), with the remaining participants reporting as being in a civil partnership (*n*=6, .2%), divorced (*n*=61, 2.9%), or cohabiting (*n*=213, 10.0%). Finally, most participants either did not take

ADM (*n*=907, 42.6%) or had been taking ADM for more than two months (*n*=774, 36.3%), with the remaining participants reporting taking ADM for either less than one month (*n*=308, 14.5%) or for less than two months (*n*=141, 6.6%). When dichotomised, this equates to *n*=1223 (57.4%) reporting to have been taking ADM and *n*=907 (42.6%) not taking ADM at the time of cCBT treatment.

3.2 Preliminary Analyses

Parametric tests were at first conducted to ensure that the parametric assumptions of normality, linearity, independence and homoscedasticity were not violated as to ensure that the models were generalisable. The assumption of normality was met as indicated by Kurtosis values ranging between -.733 and .527 across all outcome measures, thus falling within the acceptable skewness range of between 2 and -2 for regression analyses (Burdenski, 2000). Similarly, the assumptions of linearity and homoscedasticity were met as indicated by the lack of systematic relationship between errors shown in the plots of standardised residuals.

3.3 Main Analyses

3.3.1 Predicting Uptake

A BLR was completed to investigate the effects of the predictor variables on uptake, as the model includes a binary outcome variable with two levels (started session 1 or did not) and a mixture of scale and categorical predictor variables. The BLR analysis revealed that the regression model fits the data significantly better than a model based on the intercept only, as demonstrated by the non-significant Hosmer and Lemeshow chi-square test (8, *n*=2037) = 12.60; *p*=.13. Regarding the independent effects of predictors, only ADM use (χ^2 (1) =.26, *p*=.006) and age (χ^2 (1) =.02, *p*<.0001) proved to have statistically significant effects on uptake, in that absence of ADM use and older age were related to starting the BtB programme. A summary of the results of the BLR are reported in table 6.

Table 6. *A summary of the BLR analysis investigating predictors of uptake*

							95% CI for Odds Ratio	
	β	S.E. *β*	Wald's χ^2	*df*	*p*	Odds Ratio	Lower	Upper
AteH	.014	.007	3.51	1	.061	1.01	.999	1.03
Internal HLoC	.011	.008	1.91	1	.167	1.01	.995	1.03
Chance HLoC	-.004	.008	.219	1	.640	.996	.980	1.01
Doctor HLoC	.027	.016	2.90	1	.089	1.03	.996	1.06
Others HLoC	-.028	.018	2.42	1	.120	.972	.939	1.01
ADM Use (1= yes, 0= no)	.261	.096	7.43	1	.006*	1.30	1.08	1.57
Marital Status (categorical)	.014	.025	.283	1	.595	1.01	.964	1.07
Education (categorical)	.008	.079	.010	1	.920	1.01	.864	1.18
Unemployed (1= yes, 0= no)	.099	.075	1.76	1	.185	1.10	.954	1.28
Chronicity	-.026	.025	1.07	1	.301	.974	.927	1.02
Gender (1= Male, 2= female)	.103	.099	1.07	1	.302	1.11	.912	1.35
Age	.017	.004	17.7	1	.000**	1.02	1.01	1.03
Constant	-1.43	.501	8.19	1	.004*	.238	-	-

Cox and Snell pseudo R^2 = .02; Nagelkerke pseudo R^2 = .03
*p<.01
**p<.001

3.2.2 Predicting Adherence

An MLR analysis was conducted to explore the effects of the independent variables on adherence to cCBT (number of sessions completed). Independent variables included the primary predictors (HLoC and AteH variables) and secondary predictors (age, gender, education, marital status, employment status, ADM use, problem duration, and pre-treatment severity of psychological distress). A significant regression equation was found ($F(13, 2011) = 11.35$, $p<.001$), with an R^2 of .068.

In relation to the independent effects of predictors, the MLR identified AteH, 'doctors' HLoC, 'others' HLoC, age, ADM use, and pre-treatment psychological as significant predictors of adherence. Regarding AteH, more positive attitudes towards using eHealth predicted stronger adherence to cCBT (more sessions completed). Regarding the two significant HLoC variables, stronger 'doctors' HLoC beliefs predicted stronger adherence, i.e. the more people believed that a doctor has control of their health outcomes, the more they adhered to treatment, and weaker 'others' HLoC beliefs predicted stronger adherence, i.e. the less people believed other people play a role in their health outcomes, the more they adhered to treatment. In relation to sociodemographic predictors, increased age, absence of ADM use, and milder pre-treatment severity of psychological distress all predicted stronger adherence to treatment.

A summary of the results of the MLR investigating predictors of adherence is displayed in table 7.

Table 7. *A summary of the MLR analysis investigating predictors of adherence*

	Adherence		
	β	*t*	*p*
AteH	.028	2.76	.006**
Internal HLoC	.003	.265	.791
Chance HLoC	-.016	-1.37	.170
Doctors HLoC	.054	2.44	.015*
Others HLoC	-.055	-2.22	.027*
Age	.044	7.93	.000***
Gender	.016	.119	.905
Education	-.029	-.266	.790
Marital Status	.007	.199	.842
Employment Status	.125	1.22	.225
ADM Use	-.476	-3.57	.000***
Problem Duration	-.043	-1.21	.226
Pre-Treatment Severity	-.385	-3.30	.001***

*p<.01 (two-tailed)

**p<.001 (two-tailed)

3.2.3 Predicting Outcome

Two paired-samples *t*-test were conducted to investigate the significance of changes in psychological distress, anxiety and depression between pre- and mid-treatment, and pre- and post-treatment, respectively. The first paired-samples *t*-test assessed changes in psychological distress, anxiety and depression between pre- and mid-treatment, revealing significant changes in scores across all CORE-OM domains and BtB depression and anxiety measures between pre- and mid-treatment (p<.001). Similarly, the second paired-samples *t*-test assessing changes in psychological distress, anxiety and depression between pre- and post-treatment, also revealed significant changes in scores across all CORE-OM domains and BtB depression and anxiety measures between pre- and post-treatment (p<.001). Mean changes in CORE-OM Total scores between both pre- and mid- and pre- and post-treatment were equivalent to one shift in severity category as indicated by the advised cut-off points for severity ranges within a clinical population (Connell *et al*., 2007).

The results of the *t*-tests, along with the Cohen's *d* effect size for each change in outcome measure score, and the means and standard deviations for each CORE-OM subscale and the BtB anxiety and depression measures at each time point, are displayed in tables 8 (pre- to mid-treatment) and 9 (pre- to post-treatment) respectively.

Table. 8 *Means, SDs, t-test results and effect sizes of changes between pre- and mid-treatment psychological distress, anxiety and depression*

Measure	Pre-Treatment (Session 1)		Mid-Treatment (Session 5)		Change Score (Pre- to Mid-Treatment)		*t*		
	M	SD	*M*	SD	*M*	SD	(*df*=7316)	*p**	*Cohen's d***
CORE (Total)	1.84	.62	1.33	.67	.51	.52	83.67	.000	.82
Wellbeing	2.26	.86	1.62	.88	.64	.80	61.08	.000	.74
Problem Severity	2.03	.79	1.40	.79	.63	.69	78.32	.000	.80
Functioning	1.76	.71	1.30	.71	.45	.57	67.51	.000	.65
Risk	.36	.51	.17	.35	.18	.39	39.93	.000	.37
Total minus risk	1.95	.70	1.40	.72	.56	.59	80.91	.000	.79
BtB Depression	4.37	2.24	3.49	2.33	.89	2.16	34.65	.000	.39
BtB Anxiety	5.36	1.74	4.31	2.11	1.05	2.15	41.36	.000	.60

**p*<.007 (two-tailed, Bonferroni correction applied)

***Cohen's *d* effect size (Cohen, 1988; small, *d*=.2; medium, *d*=.5, large, *d*=.8)

Table. 9 *Means, SDs, t-test results and effect sizes of changes between pre- and post-treatment psychological distress, anxiety and depression*

Measure	Pre-Treatment (Session 1)		Post-Treatment (Session 8)		Change Score (Pre- to Post-Treatment)		*t*		
	M	SD	*M*	SD	*M*	SD	(*df*=4140)	*p**	*Cohen's d***
CORE (Total)	1.80	.62	1.06	.67	.73	.60	78.91	.000	-1.19
Wellbeing	2.21	.86	1.27	.85	.93	.86	69.77	.000	-1.09
Problem Severity	1.99	.79	1.12	.76	.87	.75	74.29	.000	-1.10
Functioning	1.71	.71	1.06	.70	.66	.65	65.30	.000	.92
Risk	.33	.48	.14	.33	.19	.39	32.09	.000	.40
Total minus risk	1.90	.70	1.11	.71	.79	.66	76.66	.000	-1.13
BtB Depression	4.30	2.24	2.85	2.36	1.46	2.35	40.92	.000	.65
BtB Anxiety	5.29	1.78	3.50	2.26	1.79	2.37	49.84	.000	-1.01

**p*<.007 (two-tailed, Bonferroni correction applied)

***Cohen's *d* effect size (Cohen, 1988; small, *d*=.2; medium, *d*=.5, large, *d*=.8)

A series of MLR analyses were conducted to explore the effects of the predictors on changes in severity of symptoms between pre- and mid-treatment, and pre- and post-treatment, respectively across each CORE-OM domain. The predictors included the main AteH and HLoC control variables, as well as the secondary variables of age, gender, education, marital status, employment status, ADM use, and problem duration, and the pre-treatment severity of the domain under investigation (functioning, problem severity, wellbeing, risk or total/total minus risk scores).

The MLR analyses identified 'chance' HLoC, employment status, problem duration and pre-treatment distress severity as significant predictors of changes (reductions) in psychological distress between pre- and mid-treatment across a range of distress domains. Increased severity of pre-treatment distress consistently predicted magnitude of change (greater reductions) across all CORE-OM domains. Shorter reported problem durations and weaker 'chance' HLoC beliefs also significantly predicted greater changes in psychological distress in all CORE-OM domains except for the 'risk' domain. Finally, being employed significantly predicted greater (positive) changes in all distress domains except the 'wellbeing' and 'risk' domains. Educational attainment also predicted magnitude of change in only the 'risk' domain of distress, in that higher levels of education predicted greater reductions in risk. Of note, AteH failed to predict changes across all distress domains.

A similar pattern of results was found between pre- and post-treatment changes in psychological distress and most sociodemographic predictors across distress domains; however, interestingly significant effects of iHLoC and gender were found when investigating changes between pre- and post-treatment, which were not present between pre- and mid-treatment. Greater changes in 'total' distress, 'total minus risk', and 'problem severity' domains were predicted by stronger iHLoC beliefs. Weaker 'Chance' HLoC beliefs and shorter reported duration of problems significantly predicted greater changes across all distress domains except 'risk', demonstrating the same pattern seen between pre- and mid-treatment changes. Similarly, greater severity of pre-treatment psychological distress significantly predicted greater reductions in distress across all distress domains, mirroring the pattern seen between pre- and mid-treatment. Finally, being employed significantly predicted greater reductions in psychological distress across all distress domains except risk, and being female significantly predicted greater reductions across 'total' distress, 'total minus risk' and 'functioning' domains. Again, AteH failed to predict any changes in severity of distress.

The results of the MLR analyses can be found in tables 10 (pre- to mid-treatment) and 11 (pre-post-treatment), with the pre-treatment severity predictor depending on the corresponding outcome variable.

Table 10. *MLR analyses exploring predictors of changes in psychological distress in each CORE-OM domain between pre- and mid-treatment*

	CORE-OM Domain Change Scores between Pre- and Mid-Treatment																	
	CORE Total			Total minus Risk			Functioning			Wellbeing			Problem Severity			Risk		
	β	*t*	*p*	*β*	*t*	*p*	*β*	*t*	*p*	*β*	*t*	*p*	*β*	*t*	*p*	*β*	*t*	*p*
AteH	.025	.660	.509	.030	.800	.424	.047	1.24	.214	.028	.763	.446	.012	.330	.742	-.019	-.676	.499
Internal HLoC	.059	1.56	.119	.060	1.65	.100	.033	.912	.362	.038	1.09	.275	.067	1.90	.058	-.032	-1.21	.228
Chance HLoC	-.162	-4.07	.000**	-.163	-4.26	.000**	-.150	-3.90	.000**	-.149	-4.02	.000**	-.153	-4.11	.000**	-.053	-1.85	.065
Doctors HLoC	.034	.876	.387	.046	1.22	.223	.049	1.28	.203	.020	.547	.584	.041	1.10	.271	-.011	-.404	.686
Others HLoC	.010	.253	.800	.013	.340	.734	.022	.574	.566	.011	.292	.770	.004	.115	.908	-.010	-.357	.721
Age	.053	1.23	.220	.052	1.25	.214	.057	1.37	.171	.057	1.40	.161	.042	1.04	.298	.055	1.74	.082
Gender	-.025	-.673	.501	-.008	-.221	.825	.018	.493	.622	-.051	-1.43	.153	-.023	-.643	.520	-.048	-1.81	.071
Education	.064	1.71	.088	.060	1.66	.099	.052	1.41	.159	.063	1.79	.074	.059	1.66	.098	.087	3.22	.001**
Marital Status	.019	.456	.649	.015	.375	.708	.029	.706	.480	.025	.657	.511	.001	.021	.983	-.040	-1.36	.176
Employment Status	.081	2.11	.035*	.107	2.88	.004*	.100	2.67	.008*	.057	1.60	.111	.094	2.62	.009*	-.006	-.224	.823
ADM Use	-.020	-.504	.614	-.031	-.812	.417	-.029	-.753	.452	-.013	-.342	.732	-.047	-1.28	.199	-.014	-.489	.625
Problem Duration	-.119	-3.08	.002**	-.116	-3.12	.002*	-.118	-3.14	.002*	-.124	-3.47	.001**	-.101	-2.79	.005*	-.041	-1.47	.142
Pre-Treatment Severity	.377	9.50	.000**	.432	11.4	.000**	.436	11.2	.000**	.509	13.9	.000**	.480	13.2	.000**	.781	27.3	.000**

*p<.05 (two-tailed)

**p<.001 (two-tailed)

Table 11. *MLR analyses exploring predictors of changes in psychological distress in each CORE-OM domain between pre- and post-treatment*

	CORE-OM Domain Change Scores between Pre- and Post-Treatment																	
	CORE Total			Total minus Risk			Functioning			Wellbeing			Problem Severity			Risk		
	β	*t*	*p*	*β*	*t*	*p*	*β*	*t*	*p*	*β*	*t*	*p*	*β*	*t*	*p*	*β*	*t*	*p*
AteH	.055	1.22	.223	.052	1.21	.226	.050	1.16	.246	.048	1.12	.265	.047	1.11	.266	.025	.842	.400
Internal HLoC	.121	2.71	.007*	.110	2.59	.010*	.064	1.49	.137	.120	2.84	.005	.111	268	.008*	.048	1.67	.095
Chance HLoC	-.185	-3.92	.000**	-.192	-4.30	.000**	-.170	-3.78	.000**	-.186	-4.16	.000**	-.180	-4.12	.000**	-.044	-1.43	.154
Doctors HLoC	-.033	-.698	.486	-.025	-.570	.569	-.044	-.989	.323	-.033	-.732	.464	-.003	-.078	.938	-.028	-.944	.346
Others HLoC	.060	1.26	.208	.067	1.50	.137	.073	1.62	.107	.033	.736	.462	.062	1.40	.162	-.004	-.146	.884
Age	.055	1.09	.277	.055	1.14	.257	.066	1.36	.176	.053	1.10	.273	.042	.898	.310	.059	1.80	.073
Gender	.097	2.20	.028*	.099	2.35	.019*	.117	2.76	.006*	.072	1.70	.090	.070	1.69	.092	.048	1.67	.095
Education	.039	.862	.389	.033	.775	.439	.040	.922	.357	.059	1.38	.170	.015	.358	.721	-.018	-.623	.534
Marital Status	.008	.153	.879	.004	.094	.925	.056	1.16	.247	-.018	-.371	.711	-.022	-.482	.630	-.053	-1.67	.097
Employment Status	.161	3.50	.001**	.178	4.05	.000**	.168	3.77	.000**	.090	2.08	.039*	.172	4.00	.000*	.055	1.87	.062
ADM Use	.044	.940	.348	.030	.666	.506	.039	.873	.383	.035	.785	.433	.006	.141	.888	-.002	-.060	.952
Problem Duration	-.098	-2.11	.035*	-.100	-2.27	.024*	-.095	-2.15	.032*	-.109	-2.50	.013*	-.093	-2.16	.031*	-.029	-.971	.332
Pre-Treatment Severity	.427	9.23	.000**	.485	11.0	.000**	.496	11.1	.000**	.524	12.0	.000**	.523	12.3	.000**	.854	28.4	.000**

*p<.05 (two-tailed)

**p<.001 (two-tailed)

4. Discussion

4.1 Summary of Findings

The current study explored an integrative model for understanding three factors related to cCBT response: uptake, adherence and clinical changes. An interesting pattern regarding predictors of such factors emerged. For the most part, the results support the hypotheses made based on existing relevant literature and theories, with the exception of a few key areas. Specifically, it was hypothesised that stronger iHLoC beliefs and more positive AteH would predict greater uptake in cCBT. HLoC and AteH both failed to predict uptake, and only absence of ADM use and older age were found to predict the likelihood of starting treatment, thus forcing the acceptance of the null hypothesis. Given that predictors of uptake in cCBT had yet to be investigated in this way, these findings do not contradict any existing literature, however they do pose interesting insights into sociodemographic and clinical characteristics of those most likely to start cCBT.

Regarding adherence, AteH was one of the main predicting factors of the number of cCBT sessions completed by patients, in that more positive attitudes towards accessing health information in this format (via the internet) predicted higher numbers of completed cCBT sessions (stronger adherence). This is a novel finding, given this is the first known study to investigate the influence of AteH on adherence in those completing cCBT as an intervention for mild to moderate symptoms of depression and/or anxiety. HLoC beliefs were also found to predict adherence. Stronger 'doctors' and weaker 'chance' HLoC beliefs both independently predicted higher adherence to cCBT, whilst iHLoC failed to do so. The finding regarding 'doctors' HLoC mirrors that of De las Cuevas, Peñate and Sanz (2014), albeit within a different clinical context and psychological treatment modality. De las Cuevas, Peñate and Sanz found strong 'doctors' HLoC beliefs to be the only significant HLoC domain in predicting adherence to an ADM regimen. They suggest that this finding may have occurred as a result of doctors playing a key role in the prescribing of ADM, positing that if patients perceived that they have a more active role in their treatment plan then iHLoC believes might prove significant. The finding of strong 'doctors' HLoC can perhaps in part be explained in the current study by the referring clinician. It could be argued that if one holds a strong belief that doctors have control over one's health outcomes, then one might be more inclined to follow the advice of the doctor to complete a course of cCBT. Cientanni *et al.* (2019) reported that 78.4% of the *N*=9736 referrals to cCBT services across five Scottish NHS health boards between September 2014 and April 2017 were made by GPs. Data regarding source of referral was unavailable for the current

study, however if it is assumed that a similar rate of GP referrals are mirrored across the 14 Scottish NHS health boards included in the current study between July 2017 and March 2019, then it is conceivable that advice from a doctor to complete the cCBT course may have had an influence on adherence. The finding regarding 'chance' HLoC supports research by West, Borg Theuma and Cordina (2018), again albeit within a different clinical context, in that they found weaker 'chance' HLoC beliefs to predict stronger adherence to medication regimens for chronic health conditions.

Clinical changes (reductions in psychological distress) between pre- and post-treatment was the only outcome variable to be significantly predicted by stronger iHLoC beliefs. Weaker 'chance' HLoC beliefs also predicted greater reductions in psychological distress, however this is a novel finding as no comparable research into mental health outcomes has found this effect. Other factors which predicted such improvements included pre-treatment severity of psychological distress, supporting the findings of previous studies in similar clinical contexts (Cientanni *et al*., 2019; Spek *et al*., 2007; El Alaoui *et al*., 2016), being female, supporting the findings of Chen *et al.* (2020) and Spek *et al.* (2007), and being employed, supporting the findings of El Alaoui *et al.* (2015).

In summary, the current study presents an integrative model for understanding uptake, adherence and outcome in cCBT by exploring health-beliefs together with key sociodemographic and clinical factors.

4.2 Limitations

It is not possible to make inferences regarding potential causal relationships between the predictor and outcome variables; therefore, it is not possible to claim that certain HLoC beliefs *cause* improved adherence to, or clinical outcomes of, cCBT. The current study is also unable to determine whether any clinical gains derived from completing cCBT could be further enhanced by fostering HLoC beliefs (i.e. by further reducing the strength of 'chance' HLoC beliefs, or by promoting 'doctors' HLoC beliefs), or indeed whether these gains would be stronger maintained over time if this were the case. Using a control group could have certainly allowed for greater certainty over the effects found and given an estimate as to the proportion of patients for whom symptoms may have resolved independently without intervention. It is also possible that asking questions regarding HLoC as part of the pre-treatment questionnaire may have primed participants to be thinking about their locus control within their treatment prior to

starting therapy, which may have in itself influenced the way in which they engaged. Therefore, using a control group may have allowed for the ability to test whether using a measure of HLoC and AteH in itself (simply by being asked questions regarding these constructs prior to treatment) may have influenced uptake and engagement through means of a priming effect. However, the main aims of the current study were to investigate the relationship between these constructs together with other key clinical and sociodemographic factors and uptake, engagement and outcome, and adding additional hypotheses within the current study would have diluted the testing of this model.

It is also unknown whether the construct of HLoC beliefs remained stable over the course of cCBT in those who completed the course of cCBT, or whether beliefs changed over time. It is possible that such beliefs may have shifted in light of personal evidence gained through improving one's own symptoms through completing a remote therapy.

It is also important to note that the current study was only able to analyse the change scores of those who completed at least five or all eight sessions of cCBT, therefore it is not possible to determine predictors of clinical change in those who withdrew prior to these time points. While the current study analysed predictors of adherence and changes in psychological distress over the course of cCBT in those who complete at least five or all eight sessions of BtB, the full characteristics of those who were referred to cCBT but did not start treatment are unknown. The current study was only able to access a limited amount of information regarding such patients, given the design of the study involved distributing the pre-treatment questionnaire between the point of referral and session 1 of BtB. Gaining a better understanding of the characteristics of those who do not engage past the point of referral could, for example, help to establish who is most likely to uptake cCBT.

Despite confidence that, given the size and geographical distribution of the current sample, the population is likely to be representative of the those typically accessing cCBT services, it is possible that the pre-treatment questionnaire element of the study was subject to selection bias. Self-reported measures are also subject to biases such as the social desirability effect (Arnold & Feldman, 1981), however this effect is arguably less potent in the current study given that the measures were administered remotely and anonymously.

4.3 Directions for Future Research

Future studies could seek to rectify the limitations of the current study by aiming to examine establish the relationship between adherence and clinical outcome by investigating the number of sessions of cCBT required to gain maximum effect of completing psychological therapy in this modality. Similarly, it would be interesting to compare the dropout rates seen in cCBT to those observed in face-to-face therapy from a theoretical perspective. It would be of clinical importance to establish the difference between these rates, but also to understand which factors might be related to drop out in each modality and to compare these findings.

Future studies could also explore possible interactions between HLoC and referrer, in particular it would be interesting to learn about any relationship between 'doctors' HLoC and adherence when controlling for referring clinician. Similarly, links have been made between HLoC and self-efficacy (De las Cuevas, Peñate, & Sanz, 2014), therefore it would be interesting to explore the relationship between these two constructs in the context of investigating factors involved in cCBT uptake, adherence and outcome.

As noted by Chen *et al.* (2020), there are a complex variety of factors which may be involved in engagement with computerised psychological interventions, and the current study only explores a small number of potential predictors of adherence. Examining HLoC and AteH alone as potentially important theoretical factors might be a reductionist way of exploring the intricacies of uptake, adherence and clinical changes in cCBT. Wallston (1991) maintains that health behaviours cannot solely be explained by HLoC, but that rather health values are also an important contributing factor. Therefore, the current study is perhaps limited further by the lack of exploration into health values.

4.4 Clinical Implications and Conclusions

The current study offers a unique contribution to the literature by exploring influence health-beliefs, sociodemographic, and clinical factors on cCBT uptake, adherence and clinical outcome. In this sense, the current study may help to inform 'what works for whom' and under what circumstances in relation to cCBT interventions and presents an integrative theoretical model for understanding these factors. One of the main strengths of the current study is its ecological validity. Given that the study was completed within a naturalistic, primary care setting, involving patients receiving cCBT as an intervention for mild to moderate symptoms of depression and anxiety, it is highly relevant to current clinical practice. Understanding which

factors are associated with improved uptake, adherence and clinical benefits can help guide clinical decision -making on the most appropriate treatment plan, thus potentially improving patient outcomes (Green *et al*., 2015). However, clinicians must always carefully assess the suitability of referrals to cCBT services on an individual basis, practicing in accordance with the national clinical guidelines and within the guidelines recommended by the programme itself.

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Appendix I. Author Guidelines for the British Journal of Health Psychology

Author Guidelines for the British Journal of Health Psychology

The aim of the British Journal of Health Psychology is to provide a forum for high quality research, including Registered Reports, relating to health and illness. The scope of the journal includes all areas of health psychology as outlined in the Journal Overview.

The types of paper invited are:

- papers reporting original empirical investigations, using either quantitative or qualitative methods, including reports of interventions in clinical and non-clinical populations;
- theoretical papers which report analyses on established theories in health psychology;
- we particularly welcome review papers, which should aim to provide systematic overviews, evaluations and interpretations of research in a given field of health psychology (narrative reviews will only be considered for editorials or important theoretical discourses); and
- methodological papers dealing with methodological issues of particular relevance to health psychology.

Authors who are interested in submitting papers that do not fit into these categories are advised to contact the editors who would be very happy to discuss the potential submission. All papers published in The British Journal of Health Psychology are eligible for Panel A: Psychology, Psychiatry and Neuroscience in the Research Excellence Framework (REF).

1. Circulation

The circulation of the Journal is worldwide. Papers are invited and encouraged from authors throughout the world.

2. Length

Papers describing quantitative research (including reviews with quantitative analyses) should be no more than 5000 words (excluding the abstract, reference list, tables and figures). Papers describing qualitative research (including reviews with qualitative analyses) should be no more than 6000 words (including quotes, whether in the text or in tables, but excluding the abstract, tables, figures and references). In exceptional cases the Editor retains discretion to publish papers beyond this length where the clear and concise expression of the scientific content requires greater length (e.g., explanation of a new theory or a substantially new method). Authors must contact the Editor prior to submission in such a case.

3. Editorial policy

The Journal receives a large volume of papers to review each year, and in order to make the process as efficient as possible for authors and editors alike, all papers are initially examined by the Editors to ascertain whether the article is suitable for full peer review. In order to qualify for full review, papers must meet the following criteria:

- the content of the paper falls within the scope of the Journal;
- the methods and/or sample size are appropriate for the questions being addressed;
- research with student populations is appropriately justified; and

- the word count is within the stated limit for the Journal (i.e. 5000 words, or 6,000 words for qualitative papers)

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All manuscripts must be submitted via Editorial Manager. The Journal operates a policy of anonymous (double blind) peer review. We also operate a triage process in which submissions that are out of scope or otherwise inappropriate will be rejected by the editors without external peer review to avoid unnecessary delays. Before submitting, please read the terms and conditions of submission and the declaration of competing interests. You may also like to use the Submission Checklist to help your prepare your paper.

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- For articles containing original scientific research, a structured abstract of up to 250 words should be included with the headings: Objectives, Design, Methods, Results, Conclusions. Review articles should use these headings: Purpose, Methods, Results, Conclusions. As the abstract is often the most widely visible part of your paper, it is important that it conveys succinctly all the most important features of your study. You can save words by writing short, direct sentences. Helpful hints about writing the conclusions to abstracts can be found here.
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- Tables should be typed in double spacing, each on a separate page with a self-explanatory title. Tables should be comprehensible without reference to the text. They should be placed at the end of the manuscript, but they must be mentioned in the text.
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Author, A. (2013). Title of journal article. Name of journal, 1, 1-16. doi: 10.1111/bjep.12031

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Appendix II. Thesis Protocol

Full Title: **Understanding Uptake, Adherence, and Outcome in computerised Cognitive Behavioural Therapy (cCBT) Services: Evidence from Sociodemograhic, Clinical, and Healthcare-Belief Perspectives**

Short Title: **Uptake, Adherence, and Outcome in cCBT**

Please consider this a self-declaration of use of the HRA qualitative protocol template

This protocol has regard for the HRA guidance and order of content

RESEARCH REFERENCE NUMBERS: IRAS 252821
TRIAL REGISTRY NUMBER AND DATE: (unregistered at present)
PROTOCOL VERSION NUMBER AND DATE: 0.1 06.02.19
OTHER RESEARCH REFERENCE NUMBERS: N/A
SPONSOR: University of Edinburgh
SPONSOR NUMBER: CAHSS1901/04
FUNDER NUMBER: N/A

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature: Date:

..... ……

Name: (please print):

.....

LIST OF CONTENTS

KEY STUDY CONTACTS

Chief Investigator	Miss Fabia Cientanni NHS Fife Lynebank Hospital Halbeath Road Dunfermline KY11 4UW f.cientanni@nhs.net 01383 565493 (secretaries)
Study Coordinator	Professor Matthias Schwannauer University of Edinburgh Medical Quad Teviot Place Edinburgh EH8 9AG m.schwannauer@ed.ac.uk 0131 650 3896 (secretary)
Sponsor	Ms Charlotte Smith University of Edinburgh College of Arts, Humanities & Social Sciences Room B.05, 55 George Square Edinburgh EH8 9JU Charlotte.Smith@ed.ac.uk 0131 651 1619
Joint-sponsor(s)/co-sponsor(s)	N/A
Funder(s)	NHS Fife NHS Tayside University of Edinburgh
Key Protocol Contributors	Miss Fabia Cientanni NHS Fife

	Lynebank Hospital Halbeath Road Dunfermline KY11 4UW f.cientanni@nhs.net 01383 565493 (secretaries)
Committees	N/A

STUDY SUMMARY

Study Title	Understanding Uptake, Adherence, and Outcome in computerised Cognitive Behavioural Therapy (cCBT) Services: Evidence from Socioeconomic, Clinical, and Healthcare-Belief Perspectives
Internal ref. no. (or short title)	Uptake, Adherence, and Outcome in cCBT
Study Design	The proposed study intends to use a pre-existing dataset to conduct a longitudinal cohort study design, measuring adherence at eight time points across treatment (each session of cCBT completed) and outcome at three time points, pre-treatment (T1), mid-treatment (T2), and post-treatment (T3). Uptake will be measured by comparing those referred to cCBT against those who start the treatment programme.
Study Participants	From a pre-existing dataset, participants will include individuals referred to receive cCBT as an intervention for mild to moderate depression across Scotland.
Planned Size of Sample (if applicable)	Approximately N=2000-3000
Follow up duration (if applicable)	N/A
Planned Study Period	Study is planned to terminate (including results write-up) by December 2020
Research Question/Aim(s)	The proposed study intends to establish what factors are able to predict uptake, adherence, and clinical outcome in cCBT services in order to inform service development. Therefore, the principle research question is as follows: 1. What factors predict uptake, adherence, and outcome in cCBT services?

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
NHS Fife	Salary of study coordinator Supervision time of Dr Frances Baty
University of Edinburgh	Supervision time of Prof. Matthias Schwannauer
NHS Tayside	Supervision time of Prof. Kevin Power
NHS 24	Data transfer from Mr. Christopher Wright

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor provides indemnity insurance for the project. The sponsor does not control the final decision regarding any aspects of the study, however will be consulted for advice on the process of applying for ethical approval.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

N/A

PROTOCOL CONTRIBUTORS

The sponsor provides indemnity insurance for the project. The sponsor does not control the final decision regarding any aspects of the study, however, will be consulted for advice on the process of applying for ethical approval.

The project coordinator, under supervision of NHS Fife, NHS Tayside and the University of Edinburgh, is responsible for the design of the study, conducting the study, data analysis and interpretation, manuscript writing, and dissemination of the results of the study.

Patients, service users, and/or their carers, or members of the public have not been involved in the design of this study.

KEY WORDS: Health Locus of Control (HLoC), computerised Cognitive Behavioural Therapy (cCBT), eHealth, Scottish Index of Multiple Deprivation (SIMD)

STUDY PROTOCOL

Understanding Uptake, Adherence, and Outcome in computerised Cognitive Behavioural Therapy (cCBT) Services: Evidence from Socioeconomic, Clinical, and Healthcare-Belief Perspectives

1. BACKGROUND

Internet interventions are increasingly offered across healthcare services as part of an effort to increase access to psychological therapies (Christensen & Griffiths, 2002; Doherty, Coyle & Sharry, 2012; Vis et al., 2015). Computerised Cognitive Behavioural Therapy (cCBT) offers a mechanism for reaching wide and disperse areas of the population (Vallury, Jones & Oosterbroek, 2015; Eysenbach, Mindlis, Mclellan & Vallury, 2015). This is valuable to NHS Scotland which serves remote areas such as the Highlands and Islands. Clinical psychology services in Scotland follow a 'stepped-care' model for delivering care, meaning that patients are offered the least intrusive and most effective intervention appropriate for their presenting symptoms (National Institute for Health and Care Excellence [NICE], 2006). CCBT fits within step two of this model as a low-intensity intervention for mild to moderate presentations and offers a more flexible option to receive CBT than attending clinic appointments (Foroushani, Schneider & Assareh, 2011).

However, one of the main criticisms of cCBT is that it is claimed to have poor uptake and adherence (Melville, Casey & Kavanagh, 2010; Donkin et al., 2011). A recent systematic review by Beatty and Binnion (2016) analysed data from 36 studies investigating predictors of, and reasons for, adherence to online psychological interventions. The review found several predictors of adherence to internet interventions; however, the results were either too contradictory or preliminary to draw conclusions. The reviewers state that further research is needed to establish predictors of engagement with online psychological interventions, thus providing rationale for the proposed study. The following sections offer a critical review of the literature in relation to factors which may help to explain uptake, adherence and outcome in cCBT.

Health Locus of Control

The theory of health locus of control (HLoC) offers an explanation to understand health-related decision making. The theory is based on principles of social learning theory (SLT; Rotter, 1954), which describe how behaviours are a function of both an expectancy that the behaviour

will result in a particular outcome and the value of the expected outcome. Therefore, if SLT were to be applied to engagement and potential clinical gains in cCBT, 'adherence' would be the behaviour driven by both the expectancy that they are likely to gain clinical benefits from engaging with cCBT and the perceived value of such clinical benefits. Wallston (1991) built on SLT by focusing on the expectancy element of SLT theory to create the theory of HLoC. HLoC theorises that expectancies are placed on the degree of control one has over ones' health outcomes. The degree of control is polarised by two extremes; internal and external locus of control. Those with a strong internal HLoC believe that they themselves have firm control over their own health outcomes. Whereas those with a strong external HLoC believe that they have little control over their own health outcomes. One early study found that people with high internal HLoC were more likely to contact health services to seek health-related information (Wallston, Maides & Wallston, 1976). Since then, the literature surrounding the impact of HLoC focuses on factors relating to physical health conditions, and its relevance to uptake and adherence to cCBT for those experiencing depression is unknown.

Attitudes towards eHealth

Attitudes towards eHealth may also be an important factor in driving uptake, adherence, and outcome. From a theoretical perspective, SLT would hypothesise that people are more likely to engage with a service if they believe that the service is valuable or appropriate for meeting their specific needs. However, research into attitudes towards using eHealth in a clinical psychology population is limited. A recent meta-review summarised the literature regarding patient acceptability of cCBT as an intervention (Rost et al., 2017). Rost et al. (2017) reviewed twelve systematic reviews on the acceptability of cCBT and identified a number of key factors important to patients when engaging with cCBT services, with acceptability of the intervention being consistently predictive of adherence. Similarly, El Alaoui et al. (2016) found that those who rated the credibility of the intervention more positively made greater gains from completing the intervention as measured by self-reported depression scores. However, none of the studies reviewed by Rost et al. (2017) examined attitudes towards eHealth as a mechanism for accessing healthcare; rather they focused on the acceptability of specific programmes. No literature exists to explain the relationship between attitudes towards eHealth and uptake, adherence and outcome in cCBT. By assessing attitudes toward eHealth, we aim to learn more about peoples' views towards using the internet as a means of receiving treatment. Hence, it is important to fill the gap in the literature examining the relationship between attitudes toward eHealth and engagement with psychological eHealth interventions such as cCBT.

Clinical Factors

There are also a number of clinical factors which may be involved in uptake, adherence, and outcome. For example, severity of depression prior to treatment is an important variable in relation to both engagement and outcome in psychological interventions. With regards to engagement, studies have shown that those who are more severely depressed are less likely to engage with computerised psychological interventions (Knowles et al., 2015). This may be related to one of the core symptoms of depression being marked a lack of motivation (APA, 2013; World Health Organisation [WHO], 1992). Evidence is mixed regarding the relevance of severity of psychological distress and the magnitude of clinical gains following low-intensity psychological interventions such as cCBT. In a comprehensive meta-analysis examining the influence of pre-treatment severity of depression on outcome in those receiving low intensity interventions as a treatment for depression (*N*=2470), Bower et al. (2013) found that those who were more severely depressed prior to treatment benefited from larger treatment effects than those who were less severely depressed. While some previous research found no significant interaction between pre-treatment depression severity and the therapeutic effects of cCBT (Proudfoot et al*.,* 2003) or between pre-treatment depression and treatment response as measured by changes in Beck Depression Inventory (BDI; Beck, 1961) scores (Høifødt et al., 2015), other studies have identified that those with more severe symptoms pre-treatment make greater improvements over the course of cCBT (Spek, Nyklíček, Cuijpers & Pop 20072007; El Alaoui et al., 2016). El Alaoui et al. found that high adherence to treatment and greater severity of pre-treatment depression all predicted greater reductions in self-reported depression over the course of treatment. The use of anti-depressant medication (ADM) may also predict the likelihood of starting, adhering to, and gain clinical benefits from using cCBT because ADM use may, as intended, reduce the severity of depressive symptoms (APA, 2000; Fournier et al., 2010), and may therefore lead to greater reductions in psychological distress over the course of cCBT compared to using cCBT as a stand-alone intervention. In contrast to this hypothesis, those with a history of using psychotropic medication completing cCBT have been found to make slower improvement and have higher post-treatment self-reported depression scores (El Alaoui et al., 2016). Indeed, Proudfoot et al. (2004) demonstrated that the effects of BtB did not interact with concurrent ADM use, indicating that BtB can provide clinical benefits with or without concurrent ADM use; therefore, the impact of ADM use in those completing cCBT remains unclear.

Demographic Factors

Finally, there are a number of demographic factors to consider when investigating uptake, adherence and outcome in cCBT. A study conducted by Grant et al. (2012) found that, in Scotland, those living in a greater state of socioeconomic deprivation are less likely to 'opt-in' to receive face-to-face CBT than those living in a lesser state of socioeconomic deprivation. It is possible that this pattern exists within cCBT services, however no research has yet been conducted to establish this. It has however been demonstrated that those who are more socioeconomically deprived are likely to be more psychologically distressed prior to commencing cCBT (Cientanni et al., 2017). It is important to investigate this pattern in the cCBT population to highlight potential inequalities in healthcare provision. Being female has been found to significantly predict better outcomes in internet-based CBT as measured by differences in BDI scores from pre- to post-treatment (Spek et al., 2007). In addition, a meta-analysis by Grist and Cavanagh (2013) revealed that those who are older are more likely to have poorer outcomes from cCBT. Higher educational attainment has been found to predict greater outcomes from cCBT, with the authors suggesting that this may be because cCBT as an intervention relies on literacy and self-directed learning; thus, experience in education might be an important factor in clinical gains (Spek, et al., 2007). El Alaoui et al. (2016) also found that working full-time predicted greater reductions in self-reported depression over the course of treatment, however offered no clear explanation of the reasons why.

2. RATIONALE

While the above studies provide valuable insight into a number of clinically relevant factors associated with uptake, adherence, and outcome, no study to date has considered the importance of HLoC and attitudes towards eHealth as potential predictors of these treatment-related factors in cCBT. Understanding what health belief-related and attitudinal factors may predict such variables is important in enabling clinicians to make well-informed and appropriate clinical judgements regarding referrals to cCBT services by providing a better understanding of factors likely to be associated with clinical response. This forms the core aim of the proposed study.

3. THEORETICAL FRAMEWORK

The proposed approach will address the gaps in the literature by exploring the theoretical implications of HLoC and attitudes towards eHealth within a clinical population receiving cCBT as an intervention for mild to moderate depression, as described previously.

4. RESEARCH QUESTION/AIM(S)

The proposed study aims to establish what factors are able to predict uptake, adherence, and clinical outcome in cCBT services in order to inform service development. Therefore, the principle research question is as follows:

"What factors predict uptake, adherence, and outcome in cCBT services?"

4.1 Objectives

The main objective of the proposed study is to better understand the population receiving cCBT as an intervention for mild to moderate depression.

4.2 Outcome

The outcome of the proposed project will be a greater understanding of the factors involved in predicting uptake, adherence, and treatment outcome in those receiving cCBT as an intervention for mild to moderate depression.

5. STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

The proposed study intends to use a pre-existing dataset to follow a longitudinal cohort study design, measuring adherence at eight time points across treatment (each session of cCBT completed) and outcome at three time points, pre-treatment (T1), mid-treatment (T2), and post-treatment (T3). Uptake will be measured by comparing those referred to cCBT against those who start the treatment programme.

The primary independent variables will be the extent of HLoC (scale ranging from internal to external) and attitudes towards eHealth (scale ranging from positive to negative). The secondary independent variables include socioeconomic deprivation (interval scale ranging from least deprived to most deprived), age (continuous), gender (nominal), educational

attainment (ordinal scale), employment status (nominal), marital status (nominal), ADM use (nominal), and baseline severity of psychological distress (continuous). The outcome variables include uptake (dichotomous), adherence (interval scale), and outcome (continuous).

Participants

Participants from a pre-existing dataset will include individuals referred to receive cCBT as an intervention for mild to moderate depression across Scotland.

Intervention

Currently in Scotland, cCBT is available nationally as a treatment option for mild to moderate depression provided by local NHS services. The type of cCBT offered is the 'Beating the Blues®' (BtB) programme. BtB is named specifically within the NICE and the Scottish Intercollegiate Guidelines Network (SIGN) guidelines as an appropriate intervention for those experiencing mild to moderate symptoms of depression and anxiety (NICE, 2006; SIGN, 2010). The programme consists of eight one-hour text-based self-help sessions which follow a typical cognitive behavioural therapy (CBT) structure including elements of psychoeducation, behavioural activation, and cognitive work, with printable worksheets available for patients to download. The programme is fully automated and does not require therapist support, and as such is primarily accessed by patients in their own homes but also in community settings such as libraries and outpatient clinics.

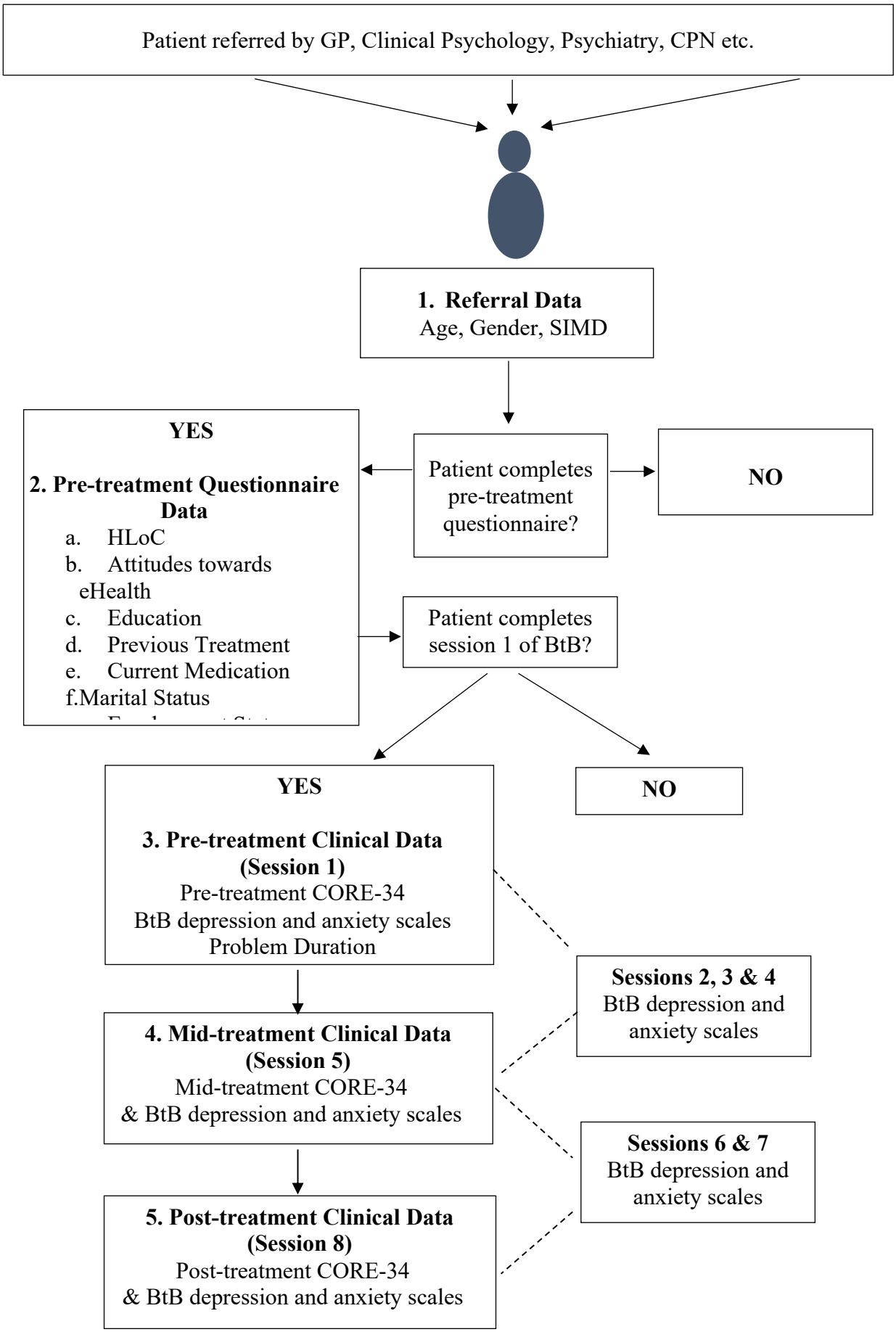
In order to gain access to the service, a referral must be made by a healthcare professional. Referral criteria for the BtB service include a suspected diagnosis of mild to moderate depression (as determined by the referring clinician), >16 years of age, must not have other significant psychological morbidity, and must not be actively suicidal. The majority of referrals are made by General Practitioners (GPs); however, referrals are also made by psychology staff, psychiatry, nursing and other services. The proposed study intends to include those referred to receive BtB as the sample population for the project, however intends to exclude those under 18 years of age on the basis that most services define an 'adult population' as being over 18 years of age, therefore it will be more comparable with other research if the small number of those under 18 years of age are excluded.

Method

The proposed study intends to use pre-existing data to answer a clinical research question. To do this, anonymised data from patients referred to the Beating the Blues service will be analysed. This data will include information from an online pre-treatment questionnaire which every participant has been sent. The pre-treatment questionnaire includes both the measure of HLoC and attitudes towards e-Health, as well as five clinical and demographic items. These include items measuring educational attainment, marital status, employment status, previous psychological / psychiatric treatment, and anti-depressant medication (ADM) use. A diagram to illustrate the pre-existing data collection time points can be found in figure 1.

Data collected from referral information, the pre-treatment questionnaire and the BtB programme will be stored on a personal account on an NHS Fife server which is backed-up daily and complies with the NHS Fife safe handling of data protocols. All electronic data will be deleted after 6 years following the completion of the project as dictated by NHS Fife data retention policy.

Figure 1. A diagram to show the five data collection points within the cCBT service of the pre-existing dataset



Data Analysis

Data will be analysed using Statistical (SPSS) software (IBM Corp, 2013). Parametric tests will at first be conducted to ensure that the parametric assumptions of normality, multicollinearity and homoscedasticity are not violated. Providing no assumptions are violated, two chi-squared tests will then be conducted to establish the relationship between one of the primary outcome variables, uptake (started BtB; yes or no), and the primary predictor variables HLoC (internal or external) and attitudes towards eHealth (positive or negative) respectively.

Following this, a Structural Equation Modelling analysis will then be conducted to investigate predictors of adherence and outcome. This analysis will test the predictive value of the two main predictor variables (HLoC and attitudes towards eHealth) and eight secondary predictor variables (socioeconomic deprivation, age, gender, educational attainment, employment status, marital status, ADM use, and pre-treatment severity of psychological distress) on adherence and outcome in cCBT services.

Further post-hoc analyses may also be required on completion of the above analyses. These might include a mediation analysis to further explore the relationship between key predictor variables, as described above.

6. STUDY SETTING

Data will be extracted from a pre-existing dataset, however the participants will have completed the BtB programme remotely. The data set is electronically will be stored on a personal account on a secure NHS Fife server.

7. SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

Participants will include adults from a pre-existing dataset who were referred to received cCBT as an intervention for mild to moderate depression. The criteria are listed below as follows:

7.1.1 Inclusion criteria

Participants will be considered for inclusion in the proposed study if:

i. They have a suspected diagnosis of mild to moderate depression

ii. They are deemed to be a suitable candidate to receive a tier 2 psychological intervention according to the stepped-care model (NICE, 2006) by the referring clinician
iii. They are aged >18 years

7.1.2 Exclusion criteria

Participants will be excluded from the proposed study if:

i. They are deemed to have significant psychological morbidity by the referring clinician (as determined by clinical judgement)
ii. They are actively suicidal

7.2 Sampling

All referrals to the BtB programme in Scotland during the inclusion period will be selected to form the sample from a pre-existing dataset.

7.2.1 Size of sample

An a priori analysis was conducted to establish the required sample size to answer the main research question: 'What factors predict engagement and outcome in cCBT services?' (two-tailed). The analysis was conducted using G* Power Analysis 3.1 software (Faul, Erdfelder, Buchner & Lang, 2009). The minimum sample size necessary to obtain adequate statistical power (1-β err. prob.=.95) to detect small effect sizes (F^2=.15), based on an alpha level of α=.05 and conducting a Linear Multiple Regression (LMR) with 10 predictor variables, was computed to be N=172.

The current number of participants who have completed the pre-treatment questionnaire is N=1305 (22/05/18). Therefore, the required sample size has been exceeded, allowing sufficient power to detect small effect sizes.

7.2.2 Sampling technique

All patients referred to receive cCBT as an intervention for mild to moderate depression in Scotland during the inclusion period will be selected to form the sample.

7.3 Recruitment

All patients referred to receive cCBT as an intervention for mild to moderate depression in Scotland during the inclusion period will be selected to form the sample. Participants will then be excluded if they meet any of the exclusion criteria.

7.3.1 Sample identification

All patients included in a pre-existing dataset referred to receive cCBT as an intervention for mild to moderate depression in Scotland during the inclusion period will be selected to form the sample. Participants will then be excluded if they meet any of the exclusion criteria. The researcher will be given the centrally held dataset by NHS 24 and will then screen the dataset for any duplicate cases and remove these. Participants will not be recruited through Patient Identification Centres (PICs). Participants will not be recruited publicly.

7.3.2 Consent

Informed consent was not gained as the current study intends to use routinely collected clinical data to answer a clinically relevant research question from a pre-existing dataset dataset. As such, no personally identifiable information will be used as part of this study.

8. ETHICAL AND REGULATORY CONSIDERATIONS

The proposed study intends to analyse routinely collected clinical data from a pre-existing dataset in order to address a clinically relevant research question. In order to ethically use this data to answer specific research questions, ethical approval will at first need to be sought. This is to ensure that the data will be used appropriately and to protect the rights of the participants who were unable to provide consent to participate in the study.

8.1 Assessment and management of risk

A Data Protection Impact Assessment (DPIA) for handling the pre-existing dataset was completed and approved locally within NHS Fife.

8.2 Research Ethics Committee (REC) and other Regulatory review & reports

Before the start of the study, a favourable opinion will be sought from the UK Health Departments Research Ethics Service NHS. Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site. All correspondence with the REC will be retained. It is the Chief Investigator's responsibility to produce the annual reports as required. The Chief Investigator will notify the REC of the end of the study. An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Amendments

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor will submit a valid notice of amendment to the REC for consideration. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC. Amendments will also be notified to NHS Fife R&D office and communicated to the participating organisations (R&D office and local research team) departments of participating sites to assess whether the amendment affects the NHS permission for that site. The Chief Investigator will be responsible for making and organising the authorisation of any amendments. The Chief Investigator will also keep a record of the amendment history and will update the protocol version number.

8.3 Peer review

Whilst no formal peer review process will be initiated for the conception of the proposed study, the research protocol has been assessed by independent academic markers as part of the fulfilment of the doctorate in clinical psychology. In addition, it is intended that the current study will be submitted to a peer-reviewed journal for publication on completion of the proposed project.

8.4 Patient & Public Involvement

No aspects of the proposed research project will actively involve patients, service users, and/or their carers, or members of the public in particular.

8.5 Protocol compliance

Accidental protocol deviations will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

8.6 Data protection and patient confidentiality

All investigators and study site staff will comply with NHS Fife Data Protection policies with regards to data storage. Anonymised data from a pre-existing data set will be shared with the Study Coordinator by the data custodian and will stored on a personal account (belonging to the Study Coordinator) on an NHS server which is backed-up daily and complies with the safe handling of data protocols. All electronic data will be deleted 6 years following the completion of the project as dictated by NHS Fife data retention policies.

8.7 Indemnity

As sponsor to the proposed study, the University of Edinburgh agrees to provide indemnity cover for this project.

8.8 Access to the final study dataset

Access to the final dataset will be available only to the Study Coordinator.

9. DISSEMINIATION POLICY

9.1 Dissemination policy

The proposed study is being conducted in partial fulfilment of a doctorate in Clinical Psychology through the University of Edinburgh (doctoral thesis). As such, the study will be listed within the University of Edinburgh 'Research Archives', which can be accessed by the general public via the University of Edinburgh website. The data used within the study is owned by each participating NHS health board.

One of the objectives of the proposed project is to write an academic article based on the findings of the study. This will be submitted to an academic journal, thus publicly disseminating the results and enhancing the current literature base to improve the shared understanding of the factors important to engagement in those referred to receive cCBT. The specific academic journal remains to be decided, however the following options are being considered; Internet Interventions, Journal of Medical Internet Research, and the Journal of Health Psychology.

A summary of the study will be submitted to the British Psychological Society (BPS) Division of Clinical Psychology's 'Clinical Psychology Forum' for further dissemination among the Clinical Psychology profession. The results of the study will also be circulated to BtB-referring GP practices, as approximately 78% of referrals to the BtB service are made by GPs.

A poster will also be made to summarise the main findings of the study in an easy-read format. It will be requested that the poster is displayed both in the local NHS and the University internal department for further dissemination of the results.

Finally, the principal researcher also intends to present the proposed research at the biennial local NHS board Clinical Psychology research conference. Any other relevant conferences or research-related events will also be explored to further disseminate the findings of the proposed study in due course. These might include NHS departmental clinical meetings, as well as wider BPS events such as the annual BPS conference. A final study report will also be completed for local NHS Fife research records.

9.2 Authorship eligibility guidelines and any intended use of professional writers

Authorship will include the following contributors for the below listed reasons in accordance with the authorship criteria defined by the International Committee of Medical Journal Editors.

1. **Fabia Cientanni**: Study conception, data analysis, and drafting of the manuscript
2. **Kevin Power:** Study conception and supervision
3. **Frances Baty:** Study conception and supervision
4. **Matthias Schwannauer:** Study conception and supervision

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Appendix III. DPIA Evaluation

DPIA

Submitting controller details

Name of controller	Fabia Cientanni
Subject/title of DPO	cCBT Research
DPO (delete as appropriate)	Margaret Guthrie

Step 1: Identify the need for a DPIA

Explain broadly what project aims to achieve and what type of processing it involves. You may find it helpful to refer or link to other documents, such as a project proposal. Summarise why you identified the need for a DPIA.
Broadly, our project aims to gain a greater understanding into the psychological factors contributing to engagement and clinical gains associated with computerised cognitive behavioural therapy (cCBT) by conducting a piece of research. Specifically, from a theoretical perspective, the study aims to explore the potential predictive value of health locus of control (HLoC) and attitudes towards eHealth on uptake, adherence and outcome in cCBT. In addition to the theoretical factors, the project will also consider the predictive value of certain demographic factors which have been found to be related to uptake, adherence and outcome. These include age, gender, socioeconomic deprivation, marital status, To achieve this, the project intends to use anonymised data from those referred to cCBT services across Scotland. Such data includes responses to an online questionnaire regarding HLoC and attitudes towards eHealth, as well as the demographic factors listed above. It was identified that a DPIA might be considered in order to process this data in the most anonymised way possible. Overall, investigating these factors will enable clinicians to make well-informed and appropriate clinical judgements regarding referrals to cCBT

by providing a better understanding of factors likely to be associated with clinical response. Overall, this will contribute to informing cCBT service development, as adherence is often considered as a success factor when evaluating healthcare services. Ultimately this will be of benefit to patients as it will provide insight into identifying those most likely to respond to and benefit from this type of intervention.

Step 2: Describe the processing

Describe the nature of the processing: how will you collect, use, store and delete data? What is the source of the data? Will you be sharing data with anyone? You might find it useful to refer to a flow diagram or other way of describing data flows. What types of processing identified as likely high risk are involved?

Pre-Treatment Questionnaire Data

Every patient who is referred to the Beating the Blues service (BtB; cCBT programme) is sent a link to an online pre-treatment questionnaire, administered via SurveyMonkey©, following a telephone conversation with their local BtB coordinator. This link contains a unique patient identifier code. The codes are held by NHS 24 and can later be linked to the data collected at the referral stage and to the data collected by the BtB programme. Participants are advised that participation in the survey is voluntary. The pre-treatment questionnaire includes both the measure of HLoC and attitudes towards e-Health, as well as five clinical and demographic items. These include items measuring educational attainment, marital status, employment status, previous psychological / psychiatric treatment, and anti-depressant medication (ADM) use. The patient is able to complete the questionnaire before commencing the intervention should they wish. The mean completion time of the pre-treatment questionnaire is 6 minutes.

BtB Data

The BtB programme collects relevant clinical information to monitor any changes in psychological distress. To do this, the Clinical Outcomes in Routine Evaluation Outcome Measure (CORE-OM) is used to assess severity of psychological distress at session 1 (pre-treatment), session 5 (mid-treatment), and session 8 (post-treatment). This is collected and stored by the BtB programme, and can be later exported and held by NHS 24.

Data will be stored and used on a secure NHS encrypted personal account on an NHS server, accessed by Fabia Cientanni. The account will be accessed at Lynebank Hospital, Halbeath Road, Dunfermline, KY11 4UW. The NHS server which is backed-up daily and complies with the safe handling of data protocols. No data will be stored or accessed on University computers. The data extracted for the purpose of this research project will not be shared with anyone outside of the research team.

Data will be deleted electronically in accordance with NHS Fife data storage and deletion protocols.

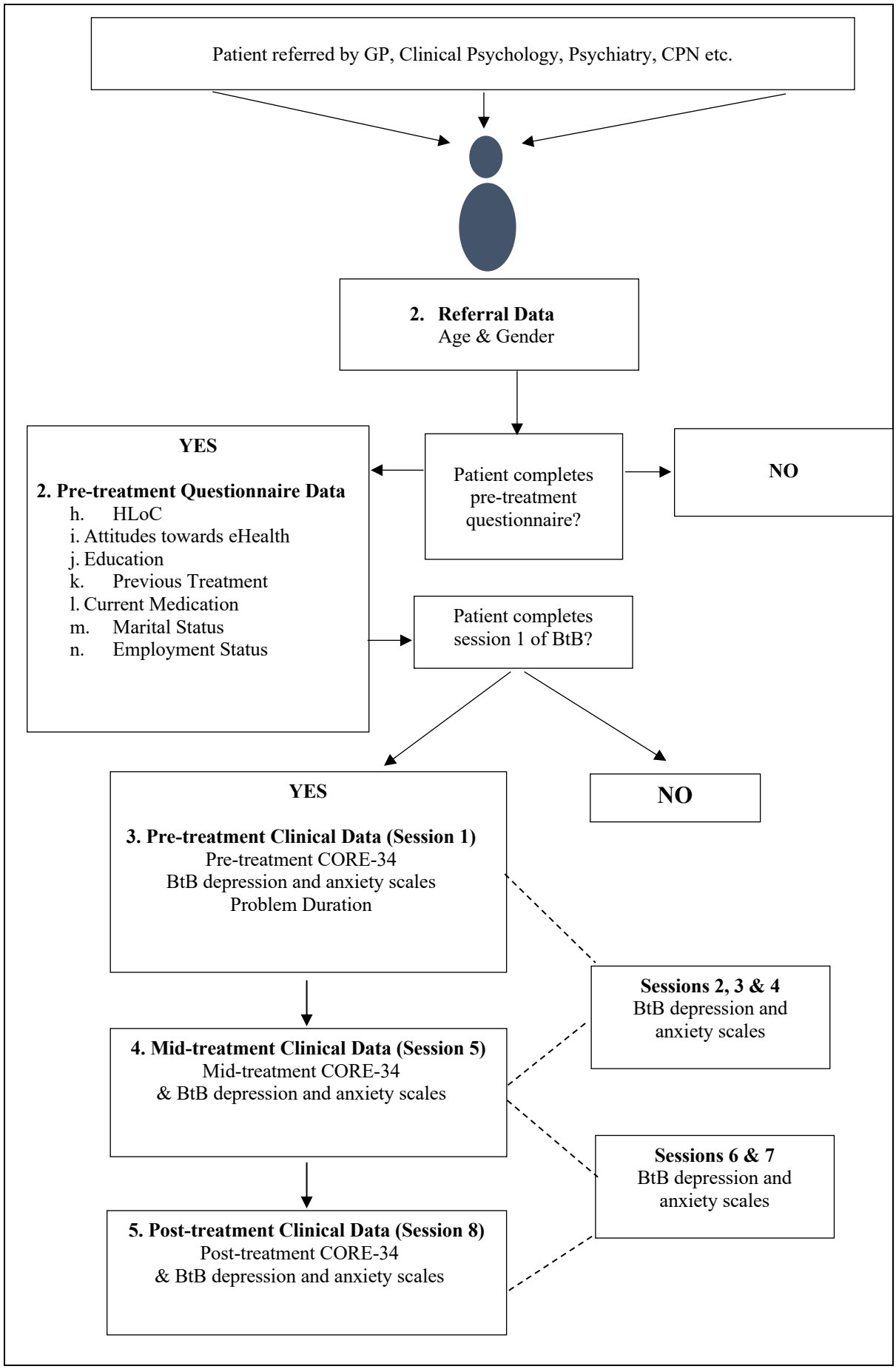
Patient referred by GP, Clinical Psychology, Psychiatry, CPN etc.
2. Referral Data
Age & Gender
Patient completes pre-treatment questionnaire?
NO
YES
2. Pre-treatment Questionnaire Data
h. HLoC
i. Attitudes towards eHealth
j. Education
k. Previous Treatment
l. Current Medication
m. Marital Status
n. Employment Status
Patient completes session 1 of BtB?
NO
YES
3. Pre-treatment Clinical Data (Session 1)
Pre-treatment CORE-34
BtB depression and anxiety scales
Problem Duration
Sessions 2, 3 & 4
BtB depression and anxiety scales
4. Mid-treatment Clinical Data (Session 5)
Mid-treatment CORE-34
& BtB depression and anxiety scales
Sessions 6 & 7
BtB depression and anxiety scales
5. Post-treatment Clinical Data (Session 8)
Post-treatment CORE-34
& BtB depression and anxiety scales

Figure 1. A diagram to show the five data collection points within the cCBT service

Describe the scope of the processing: what is the nature of the data, and does it include special category or criminal offence data? How much data will you be collecting and using? How often? How long will you keep it? How many individuals are affected? What geographical area does it cover?

The data is currently being collected under the remit of routine service data collection, however the current study proposed to use a proportion of this data for research purposes. The data includes the information described above. Data from approximately 2000-3000 participants across Scotland will be used. For the purpose of the proposed study, the data will be used once. No transferring or processing will be required after the initial transference from NHS 24 to the researcher.

The data will be kept according to the following NHS Fife policy, Health Records Retention and Destruction (GP/R8):

https://www.nhsfife.org/nhs/index.cfm?fuseaction=nhs.policyDisplay&p2sid=35712F28-A642-1F8E-27735B2916CBA7E5&themeid=E44C37C3-5056-8C6F-C003CD63C15D8FF0&objectid=4E187204-CF4C-1A82-BA7B6AEE8A9BFF1C

The above policy outlines specific parameters for storing and deleting data. Data will be stored and used on a secure NHS encrypted personal account on an NHS server, accessed by Fabia Cientanni. The account will be accessed at Lynebank Hospital, Halbeath Road, Dunfermline, KY11 4UW. The NHS server which is backed-up daily and complies with the safe handling of data protocols. No data will be stored or accessed on University computers.

Describe the context of the processing: what is the nature of your relationship with the individuals? How much control will they have? Would they expect you to use their data in this way? Do they include children or other vulnerable groups? Are there prior concerns over this type of processing or security flaws? Is it novel in any way? What is the current state of technology in this area? Are there any current issues of public concern that you should factor in? Are you signed up to any approved code of conduct or certification scheme (once any have been approved)?
The participants are unknown to the research team as they form part of a pre-existing dataset.

Describe the purposes of the processing: what do you want to achieve? What is the intended effect on individuals? What are the benefits of the processing – for you, and more broadly?
The anticipated impact of the proposed project is to gain a greater understanding into the psychological factors contributing to engagement with, and clinical gains associated with cCBT. Specifically, from a theoretical perspective, the proposed study will help to establish the potential predictive value of HLoC and attitudes towards eHealth on uptake, adherence and outcome in cCBT. This will enable clinicians to make well-informed and appropriate clinical judgements regarding referrals to cCBT by providing a better understanding of factors likely to be associated with clinical response. Overall, this will contribute to informing cCBT service development, as adherence is often considered as a success factor when evaluating healthcare services. Ultimately this will be of benefit to patients as it will provide insight into identifying those most likely to respond to and benefit from this type of intervention. A recent systematic review by Beatty and Binnion (2016) analysed data from 36 studies investigating predictors of, and reasons for, adherence to online psychological interventions. The review found several predictors of adherence to internet interventions; however, the results were either too contradictory or preliminary to draw conclusions. The reviewers state that further research is needed to establish predictors of engagement with online psychological interventions, thus providing rationale for the proposed study. It will also contribute to the limited literature base on psychological internet interventions, thus enhancing the shared understanding of predictors of engagement and outcome in this field.

Finally, the Scottish Government has identified the national implementation of cCBT services as a key objective in the Mental Health Strategy in an effort to increase the accessibility of psychological self-help resources (Scottish Government, 2017). The proposed study will serve to enrich this objective by providing a better understand the factors involved in uptake, adherence and outcome in cCBT services.

Step 3: Consultation process

Consider how to consult with relevant stakeholders: describe when and how you will seek individuals' views – or justify why it's not appropriate to do so. Who else do you need to involve within your organisation? Do you need to ask your processors to assist? Do you plan to consult information security experts, or any other experts?

The proposed study intends to analyse data from a pre-existing dataset collected as part of routine service evaluation. Therefore, in order to ethically use this data to answer specific research questions, ethical approval will at first need to be sought. This is to ensure that the data will be used appropriately and to protect the rights of the participants who were unable to provide consent to participate in the study.

Step 4: Assess necessity and proportionality

Describe compliance and proportionality measures, in particular: what is your lawful basis for processing? Does the processing actually achieve your purpose? Is there another way to achieve the same outcome? How will you prevent function creep? How will you ensure data quality and data minimisation? What information will you give individuals? How will you help to support their rights? What measures do you take to ensure processors comply? How do you safeguard any international transfers?

It is anticipated that the processing will achieve the purpose of the project, and there is no other conceivable way the achieve the same outcome than carefully considered academic research.

The quality of the data will be evaluated by an experienced academic research team. No data will be transferred internationally. Participants were informed that completing the survey was non-compulsory and that it would enable their healthcare provider to better understand and support their requirements from treatment. This was done prior to participants being sent a link to the online questionnaire. Participants were given the following written information if they chose to complete the questionnaire:

"Please complete the following survey which will allow us to better understand any support requirements you may have when completing your treatment. The questionnaire should take no more than 5-10 minutes to complete. We are interested in your honest answers and please try to answer all of the questions as best you can."

In order to ethically use this pre-existing data to answer specific research questions, ethical approval will at first need to be sought. This is to ensure that the data will be used appropriately and to protect the rights of the participants who were unable to provide consent to participate in the study.

Step 5: Identify and assess risks

Describe source of risk and nature of potential impact on individuals. Include associated compliance and corporate risks as necessary.	**Likelihood of harm**	**Severity of harm**	**Overall risk**
	Remote, possible or probable	Minimal, significant or severe	Low, medium or high
Age is considered potentially identifiable. Using this data, as opposed to age ranges, is essential in providing greater specificity to the statistical analysis.	Possible	Minimal	Low

Step 6: Identify measures to reduce risk

Identify additional measures you could take to reduce or eliminate risks identified as medium or high risk in step 5				
Risk	**Options to reduce or eliminate risk**	**Effect on risk**	**Residual risk**	**Measure approved**
		Eliminated reduced accepted	Low medium high	Yes/no
The use of date of birth information	To reduce the identifiableness of this variable, this research proposes that age (in years) is used as opposed to date of birth	Reduced	Low	Yes

Step 7: Sign off and record outcomes

Item	Name/position/date	Notes
Measures approved by:	Michelle Campbell – Information Governance and Security Advisor	Integrate actions back into project plan, with date and responsibility for completion
Residual risks approved by:	Michelle Campbell – Information Governance and Security Advisor	If accepting any residual high risk, consult the ICO before going ahead
DPO advice provided:	Summary provided below	DPO should advise on compliance, step 6 measures and whether processing can proceed
Summary of DPO advice: I've had a look at the DPIA and it seems really good, to me! Good job on outlining your research, in full but also in layman's terms. I would ask that when you receive PBPP approval that you provide us with a copy of the application and approval letter so we can sign off and record here, locally.		
DPO advice accepted or overruled by:	Fabia Cientanni	If overruled, you must explain your reasons
Comments: N/A, advice accepted		
Consultation responses reviewed by:	N/A	If your decision departs from individuals' views, you must explain your reasons
Comments: N/A		
This DPIA will kept under review by:	Fabia Cientanni	The DPO should also review ongoing compliance with DPIA

Appendix IV. PBPP Approval Letter

Public Benefit and Privacy Panel for Health and Social Care
nss.PBPP@nhs.net
www.informationgovernance.scot.nhs.uk

NHS SCOTLAND

Fabia Cientanni,
Trainee Clinical Psychologist,
Department of Clinical Psychology,
Lynebank Hospital,
Halbeath Road,
Dunfermline. KY11 4UW

Date: 27th March 2020
Ref: 1920-0057

Dear Ms Cientanni,

Re Application: Understanding Uptake, Adherence, and Outcome in cCBT Services: Evidence from Socioeconomic, Clinical, and Healthcare-Belief Perspectives
Version: v3

Thank you for your application for consideration by the Public Benefit and Privacy Panel for Health and Social Care. Your application has undergone proportionate governance review and has been approved.

This approval is given to process data as specified in the approved version of the application, and is limited to this. Approval is valid for the period specified in your application until 31st December 2020. You are required to notify the Panel Manager, via your eDRIS coordinator, of any proposed changes to your proposal, e.g. purpose or method of processing, data or data variables being processed, study cohorts, individuals accessing and processing data, timescales, technology/infrastructure.

On conclusion of your proposal, as part of NHS Scotland Governance and monitoring we will require you to complete an End of Project reporting form to demonstrate that you have complied with the obligations outlined e.g. data destruction or submission of references for publications of findings.

I would take this opportunity to remind you of the declaration you have made in your application form committing you to undertakings in respect of information governance, confidentiality and data protection. It is the responsibility of the applicant and their organisation to ensure that their study complies with current legislation at all times during the study. In particular, you should be aware that once personal has been transferred to you, that you will then become joint Data Controller as defined by data protection law, to use the data lawfully and within the purposes specified by the Panel.

Requests for access to NHS Scotland data as part of this approved application must be supported by providing a copy of your approval letter and approved application to the relevant local board contacts and/or data providers.

Please note that summary information about your application and its approval, including the title and nature of your proposal, will be published on the panel website (www.informationgovernance.scot.nhs.uk).

I hope that your proposal progresses well.

Yours sincerely,

Dr Marian Aldhous

Panel Manager
NHS Scotland Public Benefit and Privacy Panel for Health and Social Care
Email: nss.PBPP@nhs.net

Cc: Margaret Guthrie, Main contact for Lead Organisation

Appendix V. University of Edinburgh Ethical Approval Letter

SCHOOL *of* HEALTH IN SOCIAL SCIENCE

The University of Edinburgh
Medical School
Doorway 6, Teviot Place
Edinburgh EH8 9AG

Telephone 0131 651 3969
Fax 0131 650 3891
Email hiss.ethics@ed.ac.uk

22 April 2020

Dear Fabia Cientanni,

Application for Ethical Approval

Reference: CLIN724
Project Title: Understanding Uptake, Adherence, and Outcome in Computerised Cognitive Behavioural Therapy (cCBT): Evidence from Demographic, Clinical and Healthcare-Belief Perspectives

Thank you for submitting the above research project for review by the School of Health in Social Science Research Ethics Committee (REC). I can confirm that the submission has been independently reviewed and was approved on 4th April 2020.

The standard conditions of this approval are:

I. Conduct the project strictly in accordance with the proposal submitted and granted ethics approval, including any amendments made to the proposal required by the REC.

II. Advise the REC (by email to ethics.hiss@ed.ac.uk) of any complaints or other issues in relation to the project which may warrant review of the ethical approval of the project.

III. Make submission for approval of amendments to the approved project before implementing such changes.

IV. Advise in writing if the project has been discontinued.

The School's Research Ethics Policy and further information and resources are available on the School's website.

You may now commence your project; we wish you the best of luck.

Yours sincerely,

Sanni Ahonen

Administrative Secretary
School of Health in Social Science

Appendix VI. eHIQ Licence Agreement

Isis Project Number:	8768

OXFORD UNIVERSITY INNOVATION LIMITED
LICENCE AGREEMENT FOR THE REPRODUCTION ON A WEBSITE OR OTHER DIGITIALREPRODUCTION OF
CLINICAL OUTCOMES ASSESMENT QUESTIONNAIRE

PARTIES:

(1) Licensor:	Oxford University Innovation Limited with a principal place of business situated at Buxton Court, 3 West Way, Oxford OX2 0SZ
(2) Licensee:	NHS 24 Scottish Centre for Telehealth & Telecare whose registered office is at NHS 24 East Contact Centre, Norseman House, 2 Ferrymuir, South Queensferry, EH30 9QZ

This agreement (the "Licence Agreement") comprises the Commercial Terms below and the General Terms and Conditions of Licence ("the General Terms") and expressions used in the Licence Agreement have the meaning set out in the Commercial Terms or in the General Terms.

Commercial Terms:

Commencement Date	28/04/2017
the eCOA	An electronic version of the Questionnaires, an electronic Clinical Outcomes Assessment, accessible through a website, or a local application (an app) that is owned and controlled by the Licensee
Questionnaires	The health outcomes questionnaires titled: eHIQ - The e - Health Impact Questionnaire
Authors	Professor Crispin Jenkinson, Professor Sue Ziebland & Dr Laura Kelly of the University of Oxford;
Clinical Study	National study examining the impact of attitudes towards eHealth in a sample of patients referred to receive a computerized course of cognitive behavioral therapy as an intervention for mild to moderate depression.
Intended Use	For use in the study and incorporation into an electronic audit tool for the Questionnaires
Required Translations	N/a
Commissioned Translation	N/a
Term	3 years from the Commencement Date.

Territory	United Kingdom
Contact details for Licensee	Name of Manager: Christopher Wright Tel: 07825 386324 E-Mail: chris.wright@nhs24.scot.nhs.uk