Alcohol consumption and adherence to self-care behaviours in Type 2 diabetes; the

inclusion of Brief Interventions for alcohol in diabetes care

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Declaration

I declare that this literature review and research reported

is my own and not submitted for any other academic award.

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Word Count

Thesis Abstract	297
Literature Review	6,997 (references 2,147)
Research Report	11,999 (references 1,282)
Critical Appraisal	4,414 (references 547)
Total	23,411 (appendices 4,998)
Total with appendices	28,571

Alcohol consumption and adherence to self-care behaviours in Type 2 diabetes; the inclusion of Brief Interventions for alcohol in routine diabetes care

Katy Elizabeth Knott

Type 2 diabetes is a growing health problem worldwide, resulting from the body's inefficiency at utilising insulin or reduced insulin production. For those diagnosed with the chronic health condition careful self-management is required, including following complex medication regimes, exercise, diet and ongoing monitoring by clinicians. Type 2 diabetes is however characterised by poor adherence to self-care behaviours, therefore increasing risk of hypertension, weight gain, renal and nerve damage.

A systematic literature review was conducted to scrutinise literature examining psychosocial factors affecting adherence to self-care behaviours. Diverse psychosocial factors were found to affect and facilitate adherence to self-care in those with Type 2 diabetes. Strongest predictors related to social support, depression, self-efficacy and availability of financial resources. Relationship status, employment status, diabetes knowledge, health beliefs, motivation and level of education were also suggested to correlate with adherence. Coping and religion appeared equivocally related. Little research was elicited examining alcohol or smoking, however findings suggested a correlation with reduced adherence to self-care.

A quantitative study expanded upon available literature, examining the prevalence of alcohol consumption in the UK Type 2 diabetic population and whether alcohol use correlated with adherence to self-care. A small pilot study examined the efficacy of an intervention to reduce alcohol consumption, and whether this would correlate with improved self-care. Results revealed 9% of the Type 2 diabetic population were consuming alcohol at levels placing them at risk of alcohol-related health problems, with males consuming more than females. A relationship was revealed between increased alcohol consumption and decreased adherence to self-care. Findings have clinical implications regarding the inclusion of screening for alcohol use in routine diabetes care. Due to feasibility issues a small sample were recruited to the pilot study which reduced the ability to confidently infer clinical implications from findings.

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adherence to diabetes self-care for individuals with Type 2 Diabetes

Katy Elizabeth Knott

Abstract

Introduction

Type 2 Diabetes is a growing health problem carrying significant attendant risks. The disease course can be managed by patient adherence to diabetes self-care behaviours, however these are often suboptimal. Understanding the barriers and facilitators to adherence appears key to mitigate symptoms and support successful treatment and interventions. This review therefore aimed to systematically scrutinise the literature examining factors affecting adherence to diabetes self-care behaviours.

Method

A systematic search was undertaken utilising six databases, applying the search terms: 'self care', 'diabetes', 'adherence', 'self-management' and 'barriers', 'levers', 'facilitators' and 'enablers' supplemented by a manual search of key articles and contact with key researchers. Studies were included if they met an inclusion criteria and the quality of their reporting assessed with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE).

Results

Nineteen studies met criteria for review. Strongest predictors of self-care related to social support, depression, self-efficacy and availability of financial resources. Relationship status, employment status, diabetes knowledge, health beliefs, motivation and level of education were also suggested to correlate with adherence. Coping and religion appeared equivocally related. Little research was elicited examining the correlation between alcohol or smoking and adherence, however findings suggested a negative relationship.

Conclusions

Diverse psychosocial factors appear to affect and facilitate adherence to self-care behaviours. However given quality of evidence included herein further research with clearer definitions of adherence, utilising a standardized measure of this concept with clearer theoretical foundation and longitudinal in design would allow firmer causal relationships to be drawn.

Introduction

Diabetes

Diabetes is a growing health problem, with the World Health Organisation estimating 347 million cases worldwide (WHO, 2012). Almost three million people are estimated to be diagnosed with diabetes in the UK alone, with a predicted rise to five million by 2025 (Diabetes UK, 2012); the number of cases currently un-diagnosed is thought to be significantly higher (Altenburg *et al.,* 2010). Diabetes burden imposes large direct and indirect costs; as much as 15% of annual healthcare budgets worldwide are attributable to direct costs of diabetes such as medication and hospital admissions (WHO, 2011). Indirect costs appear much higher given inability to fulfil employment, adverse impact on personal relationships and increased occurrence of co-morbid conditions such as cardiovascular diseases (Ahmed *et al.,* 2006; WHO, 2011), visual loss (Balfe, 2007), amputation, nephropathy (Frandsen & Kristensen, 2002) and neuropathy (Balfe, 2007).

Diabetes is a chronic endocrine disease with two major sub-types; Type 1 and Type 2 (Diabetes UK, 2012). The latter results from the body's inability to utilise insulin effectively, known as insulin resistance, or the body not producing sufficient amounts of insulin, known as insulin deficiency (NHS, 2012), resulting in high blood sugar levels if managed incorrectly. Access to unhealthy food and the growing prevalence of obesity are argued to contribute to the increase in Type 2 diabetes diagnoses (Frandsen & Kristensen, 2002), constituting approximately 90% of diagnoses and usually considered the result of lack of exercise and excess body weight (WHO, 2011), themselves both the result of lifestyle factors.

Self-care

Within the context of outcomes for diabetes, self-care behaviours advanced to have particular influence include adherence to recommended medication regimes (Johnson *et al*., 2011; Tiv *et al.,* 2012), levels of physical activity (Johnson *et al.,* 2011), podiatric care (Altenburg *et al.,* 2010), oral medication regimes (Johnson *et al.,* 2011), diet (Lerman *et al.,* 2004), attending outpatient appointments (Johnson *et al.,* 2011), regular eye tests (Chew *et al*., 2005), smoking abstinence and keeping alcohol consumption within recommended limits (NHS, 2012).

It is suggested that adherence self-care behaviours is often sub-optimal for individuals with Type 2 diabetes. Levels of motivation to adhere to self-care behaviours and ability to make lifestyle changes are key factors in maintaining well-being. Failure to engage with self-care behaviours may result in poorer glycaemic control (Asche *et al.,* 2011), the development of micro- and macro-vascular complications and increased need for inpatient care (Ho *et al.,* 2006). The extent of adverse impact through non-adherence is unpredictable due to individual differences and impact of a variety of factors such as socioeconomic status on adherence (Innes *et al.,* 2005).

Adherence

Understanding self-care is influenced by understanding adherence. This is arguably a construct describing behaviours defined by the professional and agreed to by the patient. Adherence is considered to comprise five domains; taking medication as prescribed,

behaviour concurring with professional advice, the relationship of adherence as part of the process of care, the extent to which outcome and process targets are met or other factors influencing behaviour (Hearnshaw & Lindenmayer, 2005). As a term it is often used interchangeably with compliance (conforming to a prescribed course of treatment (Bailey & Kodack, 2011)), and concordance (associated with joint-decision making between healthcare professional and patient (Hearnshaw & Lidenmayer, 2005)). Adherence incorporates aspects of both concordance and compliance, and is promoted by WHO for use in relation to long-term chronic conditions. WHO (2003) defines adherence as 'the extent to which a person's behaviour- taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a healthcare provider' . For the purpose of the current review the WHO definition of adherence will be utilised (WHO, 2003).

There is substantial evidence that adherence to key behaviours (particularly medication (Cramer, 2004)) is poor for those with Type 2 diabetes (Osterberg & Blaschke, 2005). Yet given adherence is likely to be multi-faceted, requiring adherence to a number of different self-care behaviours themselves unrelated, it may best be considered in relation to specific self-care behaviours (Delamater, 2006). Age, co-medication, longevity of dosing (Donnan *et al.,* 2001), complexity of medication regimes and polypharmacy (Bailey & Kodack, 2011) all appear to detract from optimal adherence. Over time research has increasingly revealed psychosocial variables as stronger predictors of adherence than the aforementioned demographic variables and medication regimes; these include social support (Bailey & Kodack, 2011), occurrence of depression (Ciechanowski *et al.,* 2000), approach to coping (Smalls *et al.,* 2012) and self-efficacy (Nelson *et al.,* 2007).

Encouraging adherence to medical and non-medical aspects of care constitutes a large amount of care provided to individuals (Villas-Boas *et al., 2012*). Understanding barriers and facilitators to adherence may thus be key to enhancing diabetic control and to support successful treatment and interventions. The current review aims to examine factors facilitating and acting as barriers to adherence; therefore previous reviews examining this topic were examined to identify gaps or weaknesses in literature that would provide a focus for this review.

Previous reviews

A search of six databases for reviews (Appendix A) revealed nineteen examining adherence to self-care. Given the complexity of adherence it is unsurprising that previous reviews revealed a complex and contradictory picture with a number of factors suggested to impact adherence including medication regimes, psychosocial factors, clinician attitudes, ethnicity and culture.

Three substantive reviews emerged from the literature search, considered of better quality as they employed systematic database searches. Pun (2007) demonstrated equivocal findings from dated literature (literature included from 1986 onwards) which was not explicitly subject to quality appraisal. Nam *et al*.'s (2011) exploration of clinician variables in relation to glycaemic control found clinician attitude, beliefs, diabetes-related knowledge and their communication skills influenced diabetes self-care. The review however focused on clinician deficiency, utilised no explicit quality criteria, did not explicitly cite the definition of adherence used, and engaged in superficial analysis of a

eighty studies, as it could not give due consideration to the strengths, weaknesses or findings of each study.

A third metasynthesis of more recent qualitative literature (Gomersall *et al.,* 2011) examined psychosocial factors affecting self-care and concluded that adherence was often related to factors present in the individual's 'inner world', whilst social and political factors remained relevant. Despite the richness of the data presented in this qualitative review most studies recruited small samples, often characteristic of qualitative literature. It was felt that the current review would compliment this recent qualitative review, by focusing on quantitative literature, psychosocial factors and assessing the predictive value of these factors as a precursor to considering their amenability to change. A quantitative review would draw upon studies with larger sample sizes and increased generalisability. Previous reviews also focused upon barriers to adherence, failing to take into account facilitative factors; therefore these can be assumed to be working to a model of deficit (Vinter-Repaulust *et al.,* 2004). The strongest, most consistent findings of previous reviews related to the key facilitative role of social support and diabetes knowledge and the negative impact of polypharmacy, depression, low self-efficacy and lack of financial resources. Findings regarding employment factors and health beliefs were mixed and factors such as age, gender and ethnicity were suggested to mediate the relationship between the aforementioned factors and self-care.

Given previous diverse findings it was timely to conduct a review of factors affecting adherence. Previous reviews were weakened by a number of factors including small sample sizes, over-inclusion of studies, lack of explicit quality appraisal and a deficiency focus, therefore the current review addresses these weaknesses.

Aims

- To update previous reviews of questionable quality, including literature from 2003 onwards only as this would exclude dated literature and inclusion of literature from the past decade only would hopefully allow for a manageable yield of papers;

- To apply a consensually agreed definition of adherence to aid study comparisons;

- To include papers focusing on levers of adherence as well as barriers, to challenge a deficit model (Vinter-Repaulust *et al.,* 2004);

- To focus on psychosocial factors, given their strong predictive capacity with regard to diabetes management and their lack of previous systematic inclusion.

The question of this review was therefore formed as: 'which psychosocial factors act as facilitators or barriers to adherence to diabetes self-care for individuals with Type 2 diabetes?'.

Method

Literature search strategy

A systematic literature search was conducted between October 2012 and January 2013 of six databases, including Cochrane, EBSCO (psychinfo and psycharticles), Wiley, PubMed, Medline (OvidSp; Journals@ovid full text, Your Journals@ovid) and Web of

Science (Appendix A).

Search terms: A combination of the search terms including 'self care', 'diabetes', 'adherence', 'self-management', 'diabetes self-care', 'barriers', 'facilitators', 'levers' and 'enablers' were utilised. Where databases allowed, the search was limited to studies containing these search terms in the abstract or title only, improving the level of relevance of literature to the literature review question.

Literature was limited to articles published after 2003 from peer reviewed English language journals with adult populations (>18years) (Appendix B). Literature prior to 2003 was excluded given previous reviews had included literature from previous decades (Pun, 2007) and 1990-2009 (Nam *et al.,* 2011).

The literature search revealed 2340 relevant abstracts (see Appendix C for flow diagram). Three additional articles were identified, two through manual search of references of key articles and one through searching the list of 'relevant citations' in search databases. Professionals specialising in diabetes research and self-management programmes were contacted for relevant literature, published or unpublished, eliciting no further articles

Selection of articles

Following manual removal of duplicates, 1090 articles remained. The abstracts of the 1090 articles were manually scrutinised to reveal 106 relevant articles. Following application of an inclusion/exclusion criteria to the full-text articles 87 were excluded (see

Appendix C for details on reasons for exclusions). Nineteen relevant articles remained for inclusion.

Assessment of quality of reporting of articles

Quality of reporting of articles was gauged using the STrength the Reporting of OBservational studies in Epidemiology (STROBE; STROBE website, Moher *et al.,* 2009; Appendix D). STROBE comprises a 22-item checklist examining the title, abstract, introduction, method, results and discussion of articles with the aim of enhancing quality of article reporting (Vandenbroucke *et al.,* 2007). The STROBE checklist was utilised, with the guidance of an explanatory article (da Costa *et al.,* 2011) to provide a validated and reliable method of assessing quality of reporting.

Application of the STROBE checklist for each study is provided in Appendix E. Eight studies scored <18/32 suggesting that a significant number of items were not reported upon. A poor quality of reporting made assessment of methodological adequacy difficult. Although the STROBE did not make specific recommendations regarding a cut off score to indicate what constituted poor vs. adequate/good quality of reporting, such was the dearth of the literature that eight articles were excluded as they failed to meet over fourteen STROBE checklist items; a cut off score of 18/32 was therefore applied.

Analysis

Key features of each study were drawn out and entered into a data extraction table

with each study assigned a reference number. As studies varied greatly in sample size, design, psychosocial factor assessed and measures, a narrative synthesis of findings was conducted, gathering studies which addressed the same psychosocial factor and drawing themes in findings.

Results

Methodological Issues

Quality Assessment

Of the nineteen articles, none reported efforts to address sources of bias or reported a-priori power calculations, key in demonstrating how sample size was estimated and a factor when considering reliability of findings (Cohen, 1992) and therefore a major weakness of all studies. Other significant weaknesses included the failure of two studies to consider generalisability of findings (6, 22). Only one study explained how missing data was addressed (17), four described how analysis accounted for sampling strategies (14, 18, 21, 27), two reported efforts to address bias (15, 23) and five gave addressed sensitivity analysis (7, 14, 17, 18, 21). Fourteen studies failed to report attrition rates; of the remainder only four gave reasons for non-participation (12, 18, 22, 26) with one study including a demonstrative diagram (17). In the analysis no studies provided an indication of the number of participants with missing data for each variable.

Study characteristics

Of the studies, all but one recruited solely individuals with Type 2 diabetes; however this study analysed data of Type 1 and 2 participants separately and therefore was included (25). Studies were mainly undertaken in the United States of America (USA); of the remainder four were conducted in Europe (13, 17, 21, 25) and one in Brazil (22).

Eighteen studies provided full details of assessment measures used, their validity and reliability. Seven studies relied solely on self-report measures. Of the remainder four also extracted information from medical records, one also utilised biological data, two gained information from electronic databases, one gained information from a telephone survey and one gathered data from medical questionnaires completed by medical providers.

Thirteen studies reported samples ranging between 130 and 717 participants. Of the remainder three reported larger sample sizes, ranging between 2,572 and 21,373 and two recruited samples fewer than 100. The most common measure of adherence was a version of the Summary of Diabetes Self-Care Activities Measure, with one study using the Diabetes Self-care Activities Measure Revised and two the Dietary Subscale of the Summary of Diabetes Self-care Activities. Three studies utilised the Morisky medication adherence scale. One utilised a researcher developed questionnaire based on a combination of validated questionnaires including the Summary of Diabetes Self-care Activities Scale, Patient Activation Measure, the Problem Areas in Diabetes Scale and the Patient Assessment of Chronic Illness Scale. Two studies drew data from a large scale survey, the Behaviour Risk Factor Surveillance System (BRFSS), which consisted of a number of core

questions and questions focusing upon specific illnesses, and one utilised a researcher-developed questionnaire.

Study design

All studies utilised a quantitative methodology, with the majority being cross-sectional in design and two longitudinal.

Study Findings

Factors emergent in the literature review suggested a categorisation of psychosocial factors more amenable to change through psychological intervention as opposed to factors which may be considered more intrinsically part of an individual's being, therefore less amenable to change. Results have been divided accordingly.

Psychosocial factors amenable to change

Social support

This review identified strong evidence that social support, defined as gaining support from and having contact with friends or family, predicted increased adherence to one or a number of self-care behaviours, particularly medication regimes. Two large scale European based studies (total N=6,209), meeting a high number of STROBE checklist

items (22/32), utilised logistic regression analysis proposing poor social networks predicted lower adherence (17) and increased contact with friends facilitated improved adherence, particularly to medication regimes (21). Two further studies supported findings regarding medication adherence (15, 22), a relationship suggested to be moderated by depressive symptoms (15). A lack of family support also correlated with low adherence, associated with poorer glycaemic control (5, 14).

A significant number of papers examining the impact of social support suffered from inadequacies in reporting quality, methodological weaknesses or small sampling sizes. A small homogenous study found medication adherence, blood glucose monitoring and diet improved according to increased social support (20); this study was weakened however by its crude assessment of social support. Dietary self-management was found to be moderated by social support in two further studies (25,26). However both studies recruited small samples (26; N=53), with one recruiting working age individuals from the same company (25). A further study (16) proposed social support provided by a church environment correlated with an improved ability to adapt to living with diabetes and general well being; it however failed to report on the measure utilised to assess social support.

One study (20) found a correlation between social support and self-care in general. However on specific factors such as foot care, no correlation was found; as previously mentioned this study utilised a small homogenous sample. Despite concluding that social support positively correlated with adherence to self-care behaviours, Villas-Boas *et al.* (2012) found no correlation between social support and clinical and metabolic control variables.

Literature of greater reporting quality found level of social support correlated with higher levels of adherence to diet, exercise and medication regimes. A variation in findings may be accounted for by the variety of measures used to examine social support with some measures essentially counting number of social contacts and others considering quality of social support.

Depression

There was strong suggestion that depression, understood as a state of low mood that can negatively affect thoughts, feelings and behaviours, correlated with reduced adherence. Four studies, meeting an average of 20 items from the STROBE statement checklists, supported this finding. A large scale study (6; N=16,754) suggested an association between both minor and major depression, and a decrease in adherence to self-care behaviours including exercise, smoking and blood glucose testing, with the exclusion of foot examinations.

Two studies (total N=392) found higher depression scores correlated with lower medication adherence, less social support (15) and poorer glycaemic control (5). HbA1c was found to be 0.04% higher, indicative of higher blood glucose, for every 1-point increase in the PHQ-9 score (*P* <.005) which has significant clinical implications. A longitudinal study (7) echoed these findings, reporting a higher baseline score on the Harvard Department of Psychiatry National Depression Screening Scale (HANDS) to predict lower adherence to dietary recommendations, exercise, foot care and medication regimes.

In conclusion, strong evidence suggested depressive symptoms to correlate with adherence to self-care behaviours including exercise, smoking, blood glucose testing, medication regimes and glycaemic control. Higher levels of depression were associated with less social support with more tentative evidence suggesting a correlation with dietary recommendations and foot examination guidelines.

Self-efficacy

Self-efficacy, defined as the confidence an individual experiences that they are able to execute behaviour required to make changes (Social Cognitive Theory, Bandura, 1977), was suggested to correlate with better adherence, and it's absence with poorer self-care. Nelson *et al.* (2007) utilised regression analysis and found high self-efficacy to facilitate adherence to medication regimes, meal plans, eat a lower fat diet, physical activity, and monitor blood glucose (P<.001 for all). A longitudinal study (13) supported these findings, with poor self-efficacy found to predict poor dietary self-care.

A third study (25) found a lack of self-efficacy correlated with less regular eating and higher perception of dietary and insulin regime self-management as a burden. In conclusion a lack of self-efficacy is suggested to correlate with worse dietary self-management, and higher self-efficacy related to higher levels of adherence to medication regimes, blood glucose monitoring and physical activity.

Diabetes knowledge

Literature examining the relationship between an individual's diabetes knowledge and adherence found a correlation between low levels of adherence and a lack of diabetes knowledge. A large scale study (27; N=21,549) examining multiple predictors of adherence in a large population, found diabetes knowledge correlated with lower adherence to HbA1c testing, glucose monitoring and eye and foot examination guidelines, with those reporting no diabetes education the weakest adherers. In conclusion the correlation between lacking diabetes knowledge and poor adherence may be tentatively drawn.

Health Beliefs

Health beliefs, understood as attitudes and beliefs of an individual that predict health behaviours (The Health Belief Model; Hochbaum, 1958) were suggested to affect adherence, with a purposed relationship between 'negative' health beliefs such as scepticism and fatalism (characterised by despair, hopelessness and powerlessness), and reduced adherence. Two studies (total N=529) examined the correlation between health beliefs and adherence, with one (9) finding beliefs inconsistent with the Health Beliefs Model and Chronic Disease Model of Diabetes correlated with reduced adherence to medication recommendations. Furthermore, those with sceptical beliefs were less likely to be adherent than those holding ambivalent, accepting or indifferent beliefs. A further study (23) found health beliefs, specifically fatalism, significantly correlated with lower medication adherence, diet, exercise, blood sugar testing and diabetes knowledge, but not foot care.

After adjustment for potential covariates, including depression, the effect of diabetes fatalism remained significant and suggested to be a separate construct to depression. Both articles met a high number of STROBE items therefore provided sufficient information to allow an assessment of methodological quality of studies, and relatively confident conclusions to be drawn.

Motivation

Motivation, which could be described as a process that initiates and maintains goal-orientated behaviours, was consistently suggested to positively correlate with adherence to dietary self-care. A study of 378 participants (18) found motivation correlated with maintaining a healthy diet and blood glucose testing, but no relationship between motivation and exercise. A UK based longitudinal study (13) found that over 18 months autonomous motivation and controlled motivation were predictive of positive changes in dietary self-care.

Coping

Literature examining coping styles, understood as an individual's approach to solving personal and interpersonal problems, revealed mixed findings. Smalls *et al.* (2012) found significant correlations between emotional coping and self-care behaviours. A high number of STROBE items were met; however the study was limited as the sample comprised only African Americans, suggested to engage in high levels of spirituality (19)

therefore possibly skewing results due to their emotional faith-based beliefs. In contrast another study (16) suggested active forms of coping positively correlated with adherence and less active styles correlated with improved psychological outcomes. In conclusion literature examining coping styles appeared mixed, however it may be tentatively suggested that emotional coping positively impacts adherence.

Lifestyle factors amenable to change

Tobacco smoking

Literature suggested a relationship between tobacco smoking and lower adherence to self-care behaviours, with a large scale study (27; N=21,373) finding smoking correlated with lower adherence to foot and eye examination guidelines. This study however drew on un-weighted survey data, did not use measures specific to diabetes and recruited individuals self-identified as having Type 2 diabetes.

The impact of smoking on adherence to self-care behaviours is difficult to conclude given the circumscribed literature, however the available study pointed towards smoking tobacco correlating with reduced adherence.

Alcohol consumption

One study examined the correlation between alcohol consumption and adherence (27), reporting a relationship between heavy alcohol consumption and poor adherence to

blood glucose testing and eye and foot examinations. To note this study classified heavy

alcohol consumption as consuming two or more alcohol-based drinks per day for males,

and one for females, a measurement that may not be reliable. Due to the limited literature

conclusions regarding the impact of alcohol on adherence may only be drawn tentatively,

with current literature suggesting alcohol consumption to negatively impact adherence.

Demographic factors less amenable to change

Marital status

Literature regarding marital status suggested a positive correlation between

marriage and adherence to self-care behaviours, with a large-scale European based study

(17; N=2,572), which met a high number of STROBE checklist items, finding living with a

partner correlated with lower prevalence of smoking and higher frequency of foot

examinations, but lower adherence to glycaemic control. The negative impact upon

glycaemic control was however contradicted by another study (5), which found married

individuals had significantly lower HbA1c levels than single individuals, indicative of

better glycaemic control.

A further two studies (20,25) found a relationship between marriage and better

adherence to self-care. However these studies were limited due to their use of a small,

homogenous sample (20), limited generalisability and use of a number of un-validated

measures (25). Villas-Boas *et al.* (2012) found no significant differences in mean social

support with regard to marital status, which was proposed to indirectly impact adherence.

As this study examined an indirect relationship, the true impact could not be inferred.

In conclusion, marriage or cohabiting were found to positively correlate with adherence in studies that met a higher number of STROBE checklist items and utilising larger sample size, with better generalisability than those suggesting otherwise.

Educational attainment

Available literature reported equivocal findings regarding the relationship between level of educational attainment and adherence. A large cross-sectional study (27; N=21,373) proposed poor adherence to four key self-care behaviours, including recommended glucose monitoring, eye and foot examination guidelines and HbA1c test guidelines, to correlate with having a high school graduate or less education. Another study (20; N=89) suggested more years of education correlated with receiving more positive support behaviour, hypothesised to impact adherence. However this study also found that less satisfaction with levels of social support correlated with more years of education.

Non-medical treatment, for example diet and physical exercise, was found to have an inverse statistically significant correlation with education (22), suggesting a relationship between higher levels of education and lower adherence to non-medical aspects of care. A weak inverse correlation was suggested between social support and education, proposed to indirectly affect adherence. Weijman *et al.* (2005) found a higher level of educational level attainment associated with increased adjusting of insulin dosages and less likelihood of

regular eating. However these results had limited generalisability other than to the working-age population.

In conclusion, literature regarding the correlation between educational attainment and adherence revealed mixed findings. Quality of reporting and generalisability of findings varied to an extent that firm conclusions could not be drawn.

Employment status and work related factors

Literature examining the impact of work related factors revealed mixed findings. More hours worked per week were suggested to correlate with lower adherence, with participants reporting a high workload more likely to perceive insulin injections as a burden and more frequently adjusting dosages (25). A later study (21) similarly found working participants forgot to take medication 15% more than those who did not work, and more often took medicine late. In contradiction a large scale study (27; n=21,373) did not find a correlation between employment and eye examination adherence. The study found a positive relationship between employment and self-care, with unemployment amongst the highest factors correlating with poor adherence.

Two studies found no relationship between employment status and adherence. Tang *et al.* (2008) found no relationship between employment status and social support of participants, suggested to indirectly impact adherence; however this study utilised a small homogenous sample. Villas-Boas *et al.* (2012) found no significant differences in mean social support with regard to occupation, purposed to indirectly impact adherence.

Due to mixed findings, firm conclusions regarding the relationship between employment and adherence cannot be drawn. Work-related factors were purposed to interact in a complex manner with adherence. Factors such as depression and financial constraints associated with unemployment may moderate the relationship between work-related factors and adherence. Work related factors such as stress and high workload may negatively impact adherence. However social aspects and financial gains associated with employment may positively impact; these would require further exploration.

Financial resources

Two of the articles examining the relationship between financial resources and adherence recruiting large sample sizes (total N=25,010), met a high number of the STROBE statement items, and relatively confident conclusions can be drawn from their findings. They suggest reduced financial resources correlated with poor adherence, and increased income correlated with strong adherence. A European based study (21; N=3,637) found financial difficulties correlated with poor adherence to medication regimes (P=0.02), despite 88% of the sample reporting complementary health insurance. A second large scale study of 21,373 participants (27), conducted in the USA with no nationally funded health provision, revealed a relationship between household incomes of $20k+ and strong adherence. Another smaller study conducted in the USA (5) echoed these findings, reporting cost of following meal plans, medication, blood glucose testing and exercise correlating with reduced adherence. Cost was also found to be interrelated with depression.

In conclusion, a lack of financial resources was suggested to relate to poorer

adherence which appeared unaffected by whether a country's healthcare provision was state funded. The lack of UK based studies has implications for the application of findings to the UK population, given differing healthcare provision models.

Religion

One study exploring the impact of religion on adherence (16) found a significant relationship between the number of church services attended per month, mental wellbeing and diabetes specific well-being. The population was however drawn from a church-based randomised controlled trial, and an un-validated measure utilised to assess spirituality.

Discussion

The systematic review of barriers and facilitators of adherence synthesised the findings of nineteen studies, revealing diverse psychosocial factors associated with adherence to self-care. In applying an explicit definition of adherence and quality appraisal tool the review demonstrated significant greater methodological robustness than previous reviews, focusing upon updating prior reviews retaining a focus on psychosocial factors. The current review therefore contributes to the literature by examining the impact of a variety of psychosocial factors, their interactions, and by systematically reviewing and explicitly appraising the quality of the available literature.

A complex picture of multiple predictor variables of adherence was revealed, with some variables clustering or inter-linking with other variables. Some of the diversity may well be a facet of the breadth of psychosocial variables embraced within the studies. Given the lack of a priori use of theory to inform included studies, as well as the volume of studies examined, mechanisms thought to underpin adherence were not explored.

Psychosocial factors amenable to intervention

The review revealed a consistent facilitator of adherence as social support, which predicted increased adherence to self-care behaviours, particularly medication regimes, findings consonant with a number of earlier reviews (Bailey & Kodack, 2011; Bartels, 2004; Gomersall *et al.,* 2011; Lerman, 2004; Nam *et al.,* 2011). Strong evidence supported this relationship with two large scale studies, meeting a high number of STROBE checklist items, and fourteen further studies finding a correlation between social support and adherence.

Social support is suggested to impact adherence as those lacking in social support may not receive prompts and encouragement or support with travelling to and from appointments (Martin *et al.,* 2005). A lack of social support is proposed to correlate with depression, as those experiencing depression often withdraw from social support (Martin *et al.,* 2005), which in turn is proposed to impact adherence.

One large scale study and three further studies of good reporting quality proposed an inverse relationship between depression and adherence. Findings revealed lowered

mood to consistently be associated with reduced adherence, and to be interwoven with reduced financial resources, lower levels of social support and reduced levels of motivation to self-care. These findings support those of two previous reviews which document the strong predictor value of depression (Bartels, 2004; Bailey & Kodack, 2011) and an association between depression and unemployment (Lerman, 2004) and increased alcohol use (Lerman, 2004). As depression is characterised by reduced adherence (Cobden *et al.,* 2010) and as motivation is key in adhering to self-care the impact of depression on diabetes outcomes may be profound.

A bidirectional relationship is suggested, with diabetes predisposing depression (Bartels, 2004) and elevated rates of depression reported in this population (Ali *et al.,* 2006), which is suggested to contribute to the high rates of non-adherence characteristic of this population, increasing the risk of non-adherence by 27% (Martin *et al.,* 2008). A complex picture therefore presents of a reciprocal relationship between diabetes and depression.

Self-efficacy was also found to correlate with adherence in three studies considered of sound quality, one of which was longitudinal in design; where diminished it predicted poorer adherence, particularly to dietary self-management, consistent with previous findings (Gherman *et al.,* 2011; Krichbaum *et al.,* 2003; Lerman, 2004; Zamzam *et al.,* 2012). Reduced self-efficacy is suggested to correlate with reduced self-control and confidence to enforce behaviour change (Krichbaum *et al.,* 2003), therefore may reduce ability to make lifestyle changes.

Two studies, meeting a high number of STROBE items, examined the relationship

between health beliefs and adherence, finding scepticism, despair, hopelessness, and beliefs inconsistent with the Health Beliefs Model and Chronic Disease Model of Diabetes correlated with lower adherence. A review by Nam *et al.* (2011) supported these findings suggesting that those with more positive health beliefs displayed better adherence.

Findings regarding coping styles tentatively suggested emotional coping positively was positively associated with adherence, however studies suffered methodological weaknesses. A tentative relationship was also suggested between a lack of diabetes knowledge and low levels of adherence supported by an earlier review, suggested to correlate with lower socioeconomic status (Pun, 2007).

Given the lack of literature examining the predictive ability of alcohol consumption and tobacco smoking, only circumscribed conclusions could be drawn. Smoking was suggested to correlate with reduced adherence to self-care in a large scale study, however the study suffered from methodological weaknesses. Findings regarding alcohol suggested alcohol use to correlate with lower adherence, consonant with a previous review (Bartel, 2004). Alcohol consumption is associated with decreased motivation to adhere (Ahmed *et al.*, 2006) and increased occurrence of depression (The Royal College of Physicians, 2013), therefore interacting with numerous psychosocial factors purposed to affect adherence. A bi-directional relationship is also recognised, with heavy alcohol use predisposing diabetes (Howard *et al.,* 2004).

Factors less amenable to intervention

Two large scale studies, meeting a high number of the STROBE checklist items, and one further study examined the relationship between financial resources and adherence. Strong evidence suggested lack of financial resources to correlate with reduced adherence, with the relationship unaffected by the nature of a country's healthcare provision. These findings were consonant with previous reviews (Bailey & Kodack, 2011; Nam *et al.,* 2011; Pun, 2007), suggesting reduced financial resources resulted in an inability to meet costs associated with purchasing healthy food and transportation to appointments (Pun, 2007).

More equivocal findings regarding the relationship between marital status and adherence were presented, however one large scale study of sound quality found a correlation between marriage and improved adherence to foot-care, non-smoking, but not glycaemic control. Previous literature suggested marriage to provide social support, and families to provide enforcement and emotional support, therefore this factor may be considered associated with social support (Lerman, 2005).

Although one large scale study, scoring highly on the STROBE, revealed a significant positive correlation between employment and self-care, four further studies revealed no correlation or a negative correlation between the two, with two of these studies of low reporting quality. Factors such as depression and financial constraints associated with unemployment may moderate the relationship between work-related factors and adherence and further research should explore the relationship.

Literature revealed equivocal findings regarding the relationship between educational attainment, religious affiliation and adherence, with all reviewed papers

suffering from methodological weaknesses. Only one large scale study considered of sound quality revealed a correlation between a high school education or less and poor adherence, however the remaining literature varied in findings and quality to an extent that firm conclusions could not be drawn. A prior review suggested level of educational attainment to positively correlate with adherence and improved adjustment to diabetes interventions (Lerman, 2005). Certainly level of educational attainment may impact ability to follow complex treatment regimes, read information regarding treatment plans and understand presented information, therefore should be considered when engaging individuals in treatment and during provision of education.

One study examining the correlation between religious affiliation and adherence suggested a correlation between number of church services attended per month and adherence. This study however suffered significant methodological weaknesses. Preceding literature assigned religious affiliation under the umbrella term of 'ethnicity', purposed to positively impact adherence by creating a sense of belonging to a group (Peeters, 2010). This factor therefore requires further exploration.

Limitations

Although nineteen studies were considered of sufficient quality to be included within the review, the majority suffered from a variety of reporting and methodological weaknesses, most notably that no articles reported a-priori power calculation to determine sample sizes. Inconsistencies in sampling were noted, with small homogenous samples utilised in some studies, compromising external validity of results.

Demographic representation varied between studies, with seventeen studies reporting majority or all female samples. Mean age varied between 49.72 and 65.50 years, with one study recruiting only those over 75 years. Country of origin of studies varied, with the majority conducted in developed nations. However with US, European and Brazilian contexts, study heterogeneity is likely to be increased given differing treatment options and delivery of health care. Mean duration since diabetes diagnosis was not reported in all studies despite time since diagnosis being purposed to mediate adherence (27).

As adherence was operationalised differently between studies comparison was limited. Varied tools were utilised to measure this construct with some studies using scales specific to adherence, others relying on generic measures or utilising biological markers. Hearnshaw and Linddenmeyer (2005) suggested that varying definitions of adherence utilised in research may result in false relationships between variables and adherence being observed or failing to acknowledge the impact of variables.

Of the nineteen studies only fifteen referred explicitly to theories or models relevant to adherence, health or social context. Of these, four applied health psychology models a priori to aide understanding of issues relevant to adherence. Subsequent research should aim to ground itself in validated models to enable better understanding of issues of adherence and clinical application of findings.

Some studies examined the impact of few psychosocial variables but did not explain why these were chosen, and failed to control for other variables. Due to the complexity of adherence it appears that examining the impact of one, or few variables, does little to

increase understanding of the barriers and facilitators to adherence, and how to improve it. Research should examine the impact of a wide variety of psychosocial factors, their interactions, and control for influential variables.

Studies most commonly utilised a cross-sectional design, which limited ability to infer causal relationships. Longitudinal research is required to further explore causal relationships, complex interactions between variables, and to examine whether psychosocial factors predispose poor adherence or occur as a reaction to diabetes. This could provide indicators for clinicians regarding identifying those in need of more intensive support and to adapt interventions according to individual needs.

Although studies reported upon statistical significance of relationships between psychosocial factors and adherence, none explored clinical implications of differences. Prospective research should address this issue, as statistically significant relationships may not translate into differences meaningful for the individual. Thus basing interventions to improve adherence on statistical significance may result in little meaningful change to levels of adherence. Future reviews should also consider the role of service and clinician factors as facilitators and barriers of adherence, as this review mostly considered individual factors when examining self-management.

Clinical implications

The current review highlighted the complexities associated with defining the construct of adherence, and of facilitating adherence to self-care behaviours. Gaining a

better understanding of what constitutes good adherence would be beneficial. Assessing factors affecting adherence could aide identification of individuals at risk of demonstrating low levels of adherence (21), reducing risk of diabetes-related complications.

High rates of non-adherence persist in this population, therefore consideration should be given to the development of current or new interventions. A number of available interventions currently address issues related to social support, encouraging development of peer support and inclusion of family members to improve support networks. However the impact of social support does not appear to be explicitly addressed, therefore future interventions should include an element of education in identifying positive and negative social support, to improve support networks (20). Pun (2007) suggested improved engagement through inclusion of family therefore enhancing familial support, which should be considered integral to diabetes care.

Such is the strength of evidence regarding concurrence of depression and diabetes that interventions currently include aspects of exploring thoughts and feelings associated with diabetes. Assessment for depression and self-efficacy does not however occur as part of routine diabetes care; routine assessment would help to identify these factors. NICE guidelines regarding the provision of care for individuals with chronic physical health conditions and depression recommend provision of collaborative care (NICE clinical guideline 91, 2011). This includes the provision of co-ordinated services and a good patient-physician partnership (Martin *et al.,* 2008), and supporting the individual as a whole with psychological, health and substance misuse issues. This should in turn should improve self-efficacy in the change process and increase autonomy. Krichbaum *et al.* (2003) highlighted the importance of addressing self-efficacy, and suggested educational

interventions should include more interactive tasks with active learning. It is suggested that clinicians should be trained to support autonomy, collaborative ways of working and developing a shared understanding of treatment regimes (Boren *et al.,* 2007); this in turn should increase self-efficacy and adherence to self-care.

Essentially provision of diabetes care should be collaborative, with clinicians providing clear rationales for treatment options and simplifying regimes, to facilitate understanding, choice and responsibility-taking (Gomersall *et al.,* 2011; Nam *et al.,* 2011), and family should be involved wherever possible. As self-care requirements of individuals vary greatly and change over time, care should be reflexive to need and a 'one size fits all' approach to care should not be applied. Social, primary and secondary care should be well integrated to provide consistency of care, and consideration of the impact of service resource reduction and closure of community services should be taken.

Future research should address the limitations and weaknesses of prior research, primarily by utilising larger samples and reporting a-priori power calculations to improve external validity of findings, grounding studies in validated health psychology models and employing longitudinal designs. To enable better comparison of studies a fixed definition of adherence should consistently be used, with validated measures specific to adherence and diabetes.

Equivocal findings related to marriage or cohabiting, employment and educational attainment highlight the need for further research examining the correlation between these factors and adherence. The impact of alcohol use, smoking and religion should also be further explored. In addition, most included studies examined barriers to adherence,

working to a deficit model. This contradicts a collaborative approach to care, therefore future research should focus on facilitators of adherence.

Conclusion

Literature revealed social support and self-efficacy to be strongly associated with adherence, with depression and lack of financial resources as barriers to adherence. The direction and complexity of the relationships between these factors and adherence and the clustering and concurrence of a number of psychosocial variables requires further exploration to enable targeted interventions with the aim of facilitating improving adherence. When assessing potential barriers to and facilitators of adherence to self-care behaviours, social support, depression, self-efficacy and availability of financial resources should be prioritised on the basis of evidence to date. More rigorous research may permit better assessment of the contribution of other psychosocial factors. As a minimum, standard assessment of psychosocial factors affecting adherence should be included in routine diabetes appointments, a suggestion supported by Nam *et al*.'s review (2011).

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Alcohol consumption and adherence to self-care behaviours in Type 2 diabetes; the efficacy of Brief Interventions for alcohol in reducing alcohol consumption and improving self-care

Katy Elizabeth Knott

Abstract

Objectives

The current study aimed to address the gap in knowledge regarding the prevalence of alcohol use in the Type 2 diabetic population in the UK and the impact of alcohol on adherence to diabetes self-care. The study also aimed to examine the efficacy of a Brief Intervention for alcohol in reducing alcohol consumption and improving adherence to self-care.

Method

Due to feasibility issues a cross-sectional correlational study was conducted to examine the prevalence of alcohol use in the East Midlands Type 2 diabetic population, followed by a repeated measures pilot study to explore the efficacy of a Brief Intervention for alcohol.

Results

Data collected from 182 participants revealed 9% of the population to be consuming alcohol at levels that would place them at increased risk of alcohol-related health complications, in comparison with 21% of the general population. A correlation was reported between increased alcohol use and reduced adherence to self-care. Males consumed higher levels of alcohol, but age did not appear to affect adherence to self-care. Preliminary findings revealed a trend in reduction of alcohol consumption and improvement in adherence to self-care one month following alcohol intervention.

Conclusion

Given that 9% of the sample were consuming alcohol at levels placing them at risk of health problems, in conjunction with the correlation between higher alcohol use and lower adherence to self-care further research is warranted to explore the strength of the relationship and feasibility of inclusion of Brief Interventions into routine diabetes care. Preliminary findings suggest the integration of an alcohol screening tool into routine care, which may support clinicians to identify individuals at risk of poor adherence to self-care. This could improve efficacy of diabetes care, reduce diabetes-related complications and has significant financial implications for services due to a reduced need for treatment of complications or inpatient care.

Introduction

Diabetes

The World Health Organisation (WHO) estimated 1,765,000 cases of diabetes in the United Kingdom of Great Britain and Northern Island in 2000, and incidence was anticipated to rise to 2,668,000 by 2030 (WHO, 2011). Type 2 diabetes constitutes approximately 90% of all diabetes cases, resulting from the body becoming ineffective at utilising insulin; this is usually considered a consequence of insufficient exercise and excess body weight (WHO, 2012).

Once diagnosed with diabetes, the disease course may be altered by following key self-care behaviours (Chew *et al.,* 2005). These include adhering to recommended insulin regimes (Johnson *et al.,* 2000), physical activity (Johnson *et al.,* 2000), podiatric care (Altenburg *et al.,* 2010), oral medication regimes (Johnson *et al.,* 2000), diet (Lerman *et al.,* 2004), outpatient appointments (Johnson *et al.,* 2000), home blood glucose monitoring (Chew *et al.,* 2005), eye tests (Chew *et al*., 2005) and controlling blood glucose levels (Shai *et al.,* 2007). Sub-optimal adherence to self-care behaviour is associated with chronic diseases (Bailey & Kodack, 2011) and particularly Type 2 diabetes (Osterberg & Blaschke, 2005). Clinical implications include financial consequences for service providers due to increased need for inpatient care (Ho *et al.,* 2006) and poorer health outcomes for individuals (Asche *et al.,* 2011).

A number of demographic factors suggested to affect adherence include particularly age and gender (Gomersall *et al.,* 2011; Peeters *et al.,* 2010), with higher levels of adherence to suggested in older individuals. Psychosocial factors are also suggested to

affect adherence, with a correlation suggested between lower adherence, lack of social support, self-efficacy and financial resources and increased levels of depression (Knott, 2013).

Alcohol

Alcohol use is a growing health problem world-wide, ranking third highest contributor towards ill-health, premature death and disability (WHO, 2011). United Kingdom (UK) Government Guidelines recommend consumption of no more than 2-3 units of alcohol per day for females and 3-4 units per day for males, with at least two alcohol free days a week[2]. Exceeding this level on a regular basis may result in health difficulties including liver problems, high blood pressure, increased risk of heart attack, fertility problems and increased risk of certain cancers (NHS, 2011). Recommended alcohol guidelines for individuals with diabetes are more varied, with different health sites offering varying advice: 1 unit a day for females and 2 units a day for males (National Institute on Alcohol Abuse and Alcoholism, 2003; American Diabetes Association, 2010): 2 units a day for females and 3 units a day for males (Diabetes UK, 2009c).

Alcohol and diabetes

Whilst to date lifestyle factors other than alcohol use have dominated diabetes

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[2] A unit is considered in the UK to constitute of a 25ml measure of spirit, 125ml of wine or half a pint of regular strength lager. (obtained from NHS issue guidelines; NHS website, 2011).

research, a substantial body of literature reports alcohol consumption to adversely affect self-care. Alcohol consumption is suggested to negatively impact glycaemic control (van de Wiel, 2004) interfering with the process of gluconeogenesis, a sensitive process within individuals with diabetes. Diabetes education sites such as Diabetes UK are unclear regarding the level of alcohol consumption required to result in hypoglycaemia, citing factors such as food intake and type of alcohol as mediators (Diabetes UK, 2009a). Evidence suggests that if fasting when alcohol is consumed the likelihood of hypoglycaemia is increased as blood glucose levels are already low (Engler *et al.,* 2010). This may occur some hours after alcohol consumption (van de Wiel, 2004) resulting in delayed coma.

Longer term risks of alcohol use in this population include increased risk of hypertension (van de Wiel, 2004), weight gain due to the calorific content of alcohol (Diabetes UK, 2009b), and increased likelihood of renal or nerve damage (nephropathy or neuropathy), or exacerbation of existing problems (Engler *at al.,* 2010).

Patterns of alcohol use have been related to poorer adherence to self-care: given that individuals with diabetes require high levels of motivation to adhere to self-care behaviours (Johnson *et al.,* 2000) motivation is key. Increased alcohol use is associated with poorer adherence to medication regimes (Chew & Young, 2005) and may affect pharmacological properties of medication, either antagonistically or synergistically, with unpredictable consequences for glucose control (Weathermon & Crabb, 1999). Poor adherence to diet, self-monitoring of blood glucose, oral medications and appointment-keeping is also reported, with Johnson *et al.* (2000) reporting that alcohol consumption within the previous 30 days correlated with reduced adherence. A further study (Ahmed *et al.*, 2008) found

reduced adherence to self-care from as little as one drink per day, with those who consumed more alcohol found to adhere less. In a critical literature review (Knott, 2011) ten studies demonstrated a negative relationship between alcohol and adherence: the impact on adherence varied according to the specific self-care behaviour, with reduced access to medical services being cited as being most frequently affected.

It is suggested that low levels of alcohol consumption may positively affect those with diabetes, most notably reducing the risk of developing cerebrovascular and coronary diseases (Chew *et al.,* 2005; Johnson *et al.,* 2000) and potentially improving glycaemic control (Ahmed *et al.,* 2008). However, it appears that the multitude and magnitude of risks associated with alcohol use in this population far outweigh the benefits.

To date, sparse literature has examined the extent and patterns of alcohol use of the Type 2 diabetes population in the UK. An exploration of self-help fora on diabetes websites revealed debates and queries regarding alcohol use are prominent and unresolved (diabetessupport.co.uk, 2013). Given the lack of consensus regarding advice on alcohol use for individuals with diabetes (van de Wiel, 2004), and varying guidelines, some individuals may unknowingly be consuming above safe levels thereby putting themselves at risk of the aforementioned problems.

Advice given to individuals with diabetes regarding alcohol use by healthcare professionals and services appears key. A scoping search of patient information, leaflets and diabetes education sites (American Diabetes Association, 2010; Diabetes UK, 2009; Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND), 2008; NHS, 2011), revealed limited information or education regarding

alcohol use in this population. NHS (2012) limits its guidance to advising those with Type 2 diabetes to drink "in moderation" but fails to explicitly define this in terms of units of alcohol. DESMOND support staff to offer structured patient education programmes for those with Type 2 diabetes in the UK; however information regarding alcohol was found to be lacking unless advice was in relation to the calorific contents of alcoholic beverages.

Alcohol Screening and Brief Interventions for alcohol

NICE guidelines (2010) recommend routine alcohol screening and opportunistic Brief Interventions (BIs) for all individuals over the age of 16 who come in contact with healthcare settings, and some non-healthcare settings such as educational services, as part of the *National Alcohol Harm Reduction Strategy* (2004). BIs for alcohol are defined as: 'opportunistic brief advice and information given regarding alcohol and its risks' (National Treatment Agency; NTA, 2006).

Research reviewed by the NTA suggested BIs conducted in a variety of healthcare settings are successful in reducing alcohol consumption to within 'safe drinking levels' in 'hazardous and harmful drinkers' (terms now exchanged for 'increasing risk and higher risk') and the effects may last between two and four years (Raistrick *et al.,* 2006). Evidence suggests the efficacy of BIs in reducing alcohol consumption in primary care settings and physical health outpatient clinics (NTA, 2006). The NTA (2006) described two types of BIs: Simple BIs taking no more than 15 minutes and consisting of information and advice about alcohol and its risks: and Extended BIs taking 20-30 minutes and including structured therapies and possibly more than one session. Throughout the current study, when the term

BI is referred to, it will be in relation to Simple BIs.

Kaner *et al.'s* (2007) meta-analysis of 22 randomised controlled trials demonstrated that on average, those in General Practice and Emergency Care settings receiving 5-15 minute BIs drank significantly less alcohol at one year follow-up than control groups. Project TrEAT (Trial of Early Alcohol Treatment) demonstrated a reduction in alcohol consumption following BI in adults attending community based primary care practices in the USA, resulting in improved health status, lesser use of health care and reduced mortality rates (Fleming *et al.,* 2002).

NICE advise professionals working within all healthcare, and some non-healthcare settings, receive training in BIs and the opportunistic provision of 5-15 minute BIs for all service users (2010). The NTA advise on the use of BIs in most healthcare settings as both cost-effective and a clinically viable way of reducing the alcohol consumption of 'increasing risk' to 'higher risk' drinkers to within safe levels whilst raising awareness of alcohol misuse (2004). The term 'increasing risk' is operationally defined as a score of between 8 and 15 on the Alcohol Use Disorders Identification Test (AUDIT; Barbor *et al.,* 2001), with suggested increased risk of health difficulties, predisposing numerous medical conditions. The term 'higher risk' is defined as a score of between 16 and 19 on the AUDIT, with an even higher risk of health difficulties in comparison with 'increasing risk' drinkers.

BIs are advocated for raising awareness of the risks of alcohol consumption for those with diabetes and have been found to significantly enhance levels of self-care (Ramsey *et al.,* 2010). In conclusion it would make sense that if regular BIs help to

maintain safe drinking levels in this high risk population and improve adherence to self-care, this intervention should be carried out routinely by Diabetes Nurses and Practice Nurses within regular scheduled appointments when other life-style factors such as dietary intake and exercise are addressed. The role of health care professionals is key in identifying opportunities to provide relevant advice and information to assist those with diabetes to make informed choices regarding their alcohol consumption and best manage their diabetes.

A pilot study examining the efficacy of performing BIs combined with feeding back results of carbohydrate-deficient transferrin (CDT; an alcohol biomarker) tests found the use of BIs reduced alcohol consumption (Fleming *et al.*, 2004). Following a base-line interview, 151 participants with Type 2 diabetes and/or hypertension were randomly assigned to a BI or Treatment As Usual group (TAU). Two 15 minute BIs were performed by a Nurse Practitioner or a Physician Assistant at one month intervals, with tasks given to complete at home followed by two five minute telephone follow-ups and follow-up interviews at two, four and twelve months post baseline. The BI group demonstrated a 16% reduction in alcohol use in comparison to the TAU group, the latter of which demonstrated no change. However the feasibility of incorporating the intervention at such regular intervals with follow-up calls into routine practice in the UK remains unknown. Furthermore the study did not address the impact that alcohol may have on diabetes self-care behaviours and therefore failed to consider the clinical implications in relation to self-care.

A small scale USA based study (Ramsey *et al.*, 2010), compared two groups of 'moderate-light drinkers' with diabetes: a BI group and a TAU group, on measures of

alcohol consumption and adherence to self-care. Adherence was measured using the

Summary of Diabetes Self-Care Activities Measure (SDSCA33), Blood Alcohol Levels

(BAL) and Time Line Follow Back (TLFB, Sobell & Sobell, 1992, as cited in Litten &

Allens, 1992) were utilised to measure alcohol consumption at baseline and at three and six

month follow-ups. The BI group received a 50 minute 'Brief' Intervention performed by

Doctoral level Clinical Psychologists. Personalised feedback was also given regarding risk

in relation to family history and diabetes and participants received written feedback

summarizing what had been discussed. At six-month follow-up the BI group revealed a

reduction in the amount of alcohol consumed and an improved adherence to self-care

behaviours, in particular diet and exercise, and a reduction in smoking. A reduction in the

percentage of heavy drinking days and frequency of drinking was also reported.

Both aforementioned studies (Fleming *et al.,* 2004; Ramsey *et al.,* 2010) were

conducted in the USA, with no similar research in the UK. Given likely cultural

differences due in the main to differences in healthcare provision and attitudes to alcohol

consumption, it is unknown whether the results of these studies are applicable to the UK

population; a UK-based study is thus timely. In addition, Ramsey *et al.'s* (2010) study

administered 50 minute BIs, not in line with NTA guidelines nor thought viable to perform

in busy Diabetes Clinic or GP surgery environments. Neither studies examined the

prevalence of alcohol use in a large population, and findings regarding the impact of

alcohol on adherence to self-care in Ramsey *et al.* (2010) had limited generalisability due to

the small sample size.

If BIs were found to reduce alcohol consumption in those with Type 2 diabetes in

the UK which in turn improved adherence to self-care behaviours, clinical implications

include that support and advice regarding alcohol consumption should be offered routinely within diabetes check-up appointments. Alcohol screening and BIs are recommended for this patient population (Engler *et al.,* 2010), with Fleming *et al.* (2004) suggesting the training of one or two nursing staff within each diabetes clinic to provide BIs for alcohol for those identified as 'risky' drinkers.

The current study comprised two stages:

Stage 1

Examined the percentage of the Type 2 diabetes population identifying as 'increasing risk' to 'higher risk' drinkers according to the AUDIT, the definitions of which have previously been outlined (Barbor *et al.,* 2001; Appendix F), and the extent to which alcohol consumption impacted adherence to diabetes self-care behaviours according to the SCI-R (La Greca, 1992; Appendix G).

Stage 2

Examined the efficacy of using BIs for alcohol with the Type 2 diabetes population including the impact on alcohol consumption and the impact on adherence to diabetes self-care behaviours (using the AUDIT and SCI-R).

Rationale for originality of the current study

- The prevalence of alcohol consumption in those with Type 2 diabetes in the UK was largely unknown.

- The impact of alcohol consumption on adherence to diabetes self-care behaviours was greatly under-researched.

- No prior UK based studies within this population had been conducted examining the efficacy and feasibility of utilising BIs for alcohol, in line with NICE (2010) guidelines (previous studies have offered too long an intervention to be classified as a BI according to NICE).

- Previous research had recruited a combination of participants with Type 1 and Type 2 diabetes or included individuals without a diabetes diagnosis; this was the first study to focus on those with Type 2 diabetes.

Aims

Stage 1

1. To examine the percentage of individuals in a Type 2 diabetic population identifying as 'increasing risk' to' higher risk' users of alcohol according to the AUDIT.

2. To examine demographic variables such as age, gender or ethnicity that may account for any differences in adherence to self-care behaviours or alcohol

consumption (Demographic Pro-forma; Appendix H).

3. To assess levels of adherence to key diabetes self-care behaviours using the SCI-R.

4. To examine the correlation between level of alcohol consumption and adherence to self care behaviours.

Stage 2

1. To assess the impact of BIs for alcohol on alcohol consumption and adherence to diabetes self-care behaviours in a pilot group, using the SCI-R and AUDIT.

Research Questions and Hypotheses

Stage 1

1. What percentage of those with Type 2 diabetes are using alcohol to 'increasing risk' to 'higher risk' levels according to the AUDIT?

   Hypothesis A) Measures of patterns of alcohol use will show numbers of 'increasing risk' to 'higher risk' drinkers similar to that of the general population.

2. What is the correlation between alcohol consumption and adherence to self care behaviours; what impact will age have on self-care and gender have on alcohol consumption?

   Hypothesis B) Increased alcohol consumption will correlate with lower

adherence to self-care behaviours.

Hypothesis C) Individuals within the older age groupings will demonstrate

better adherence to self-care behaviours than those within the younger

age groupings (as suggested by Peeters *et al.,* 2010).

Hypothesis D) Females would score significantly less than males on the

AUDIT: the General Lifestyle Survey (Office for National Statistics,

2009) suggested 26% of males but only 18% of females drank over

government recommended levels of alcohol consumption.

Stage 2

3. What impact will BIs for alcohol have on patterns of alcohol use and adherence

to diabetes self-care behaviours?

Hypothesis E) Following a BI for alcohol participants will see a reduction in

their AUDIT scores at one month follow-up.

Hypothesis F) A reduction in AUDIT score at one month follow-up will

correlate with increased adherence to diabetes self-care behaviours.

Ethics and research Governance

The current study was reviewed and approved by the University of Leicester,

a Multi-site National Research Ethics Service (NRES) and the local National Health

Service Research and Development office (NHS R&D) (all approval letters included in

Appendix I). The study was also reviewed by a University-based Service User Group.

Two independent clinicians specialising in the area of diabetes reviewed the study for the

purpose of the National Institute for Health Research Portfolio adoption (NIHR)

(acceptance letter included in Appendix I).

Methodology

Stage 1

Design

A quantitative, cross-sectional, correlational design was utilised to examine the

relationship between alcohol use, adherence to diabetes self-care and demographic

variables. Due to time constraints a longitudinal design could not be utilised; this would

have provided an indication of causal relationships. Variables measured included

adherence to diabetes self-care behaviours, alcohol use and demographic variables.

Participants

Power Analysis

Sparse prior research had examined prevalence of alcohol use in individuals with

Type 2 diabetes. Alcohol use was therefore estimated to be on par with the general

population and data from the Alcohol Concern *Alcohol Harm Map* (n.d. which obtains its

data from the General Lifestyle Survey, Office for National Statistics, 2009) which

suggested 21% of the population in the East Midlands of England consumed over

government recommended levels of alcohol (weekly: 21 units for males; 14 units for

females).

An a-priori power analysis was conducted to calculate sample size required to

enable an estimation of alcohol consumption to be made, with sufficient statistical power,

(Daniel, 1999, as cited in Naing, Winn & Rusli, 2006). This calculation included a 95%

confidence interval, an error probability of 0.5 and predicted 21% of the sample to be

consuming over recommended levels. The predicted total sample size required was

therefore 255 participants.

Identification of participants

The patient sample was identified by Practice Managers or Research Nurses from

the clinical databases of three GP Surgeries, a Specialist Diabetes Clinic and from

individuals on a local Diabetes Research List. Several sources of recruitment ensured an

adequate sample size.

Exclusion and Inclusion criteria

Inclusion: Individuals were deemed suitable to include if they: were diagnosed with Type 2

diabetes; were over the age of 18 but less than 75 years; were attending a Diabetes Clinic or

GP surgery; had fluency/ literacy skills in the English language sufficient to read

information sheets; and consented to participate and complete the measures.

Exclusion: Individuals were excluded if they: were under the age of 18 or over 75 years; were without a diagnosis of Type 2 diabetes; refused to complete the measures; were lacking fluency/literacy skills in the English language; and lacked the capacity to consent.

Demographic Information

Of the 182 participants included in the analysis, 41.8% were female (see Appendix J for demographics table separated according to recruitment source). Most participants fell within the >56 year age bracket (71.4%), of the remainder 22.5% were in the 41-55 year age bracket and 6% in the 26-40 year age grouping. Most participants self-identified as White British (69.2%), with 24.7% identifying as Asian Indian, and the remainder identifying as Pakistani, any other Indian background, Caribbean, African and any other White background. Most participants identified as married (65.9%), with the remainder identifying as single, co-habiting, divorced, separated or widowed. Nearly half of all participants identified as retired (46.7%), with 30.8% in full-time employment, 6% in part time employment, 5.5% self-employed and 8.2% unemployed or unable to work.

The percentage of individuals in each age group in the sample were in line with estimates that approximately 38% of the general population diagnosed with diabetes are above 55 years of age, approximately 7% fall within the 41-55 age group and an around 2% fall within the 26-40 age group (to note figures include Type 1; The Information Centre, 2011). The gender distribution of the sample was also in line with estimates that men receive slightly more diagnoses than women, 6.3% versus 5.3% of the general population (to note figures include Type 1; Welsh Health Survey, 2010). The sample was not however representative of the estimated ethnic build-up of the Type 2 diabetic population; purposed

to be six times more common in individuals of South Asian descent and three times more common in those of Afro-Caribbean or African origin (The Information Centre, 2006). The sample in the current study therefore did not represent the estimated increased prevalence in certain ethnic groupings.

Materials

Measures

1. Self Care Behaviour

The SCI-R (Appendix G) was utilised to measure adherence to diabetes self-care including maintenance of glucose levels, dietary intake, medication adherence, attendance of medical appointments and exercise. It has suitable sensitivity and validity and had previously been utilised in studies examining adherence to self-care behaviours in those with diabetes (Weinger *et al.,* 2005) and been found reliable for use in the UK (Khangram *et al.,* 2013). It is a 15-item self-report measure. An average score from all items was calculated, then converted into a 0-100 point score. It was recommended that the scoring of items 3, 13 and 15 were not included for individuals with Type 2 diabetes (Bentler, 1990; as cited in Kangram *et al.,* 2013). Diabetes self-care was operationally defined as the overall 0-100 point score calculated from the SCI-R. Written consent was gained from the author for the use of the measure.

2. *Pattern of Alcohol Consumption*

The AUDIT (WHO, 1982; Appendix F) was used to identify level of alcohol use: categorised as 'lower risk', 'increasing risk', 'higher risk' or 'possible dependence'. This form of measuring alcohol use is considered sensitive in detecting current level of alcohol intake (Dybek *et al.,* 2006) and is recommended for use in primary care, in specialised alcohol services and in research studies (Barbor *et al.*, 2001). The 10-question screening tool asks about drinking frequency and intensity and signs of possible alcohol dependence. The measure was also used in the current study as a screening tool to assess eligibility to participate in Stage 2 of the study. Level of alcohol consumption was operationally defined through calculating a total score, and identifying which category this fell within: 0-7 = 'lower risk', 8-15 = 'increasing risk', 16-19 = 'higher risk', 20+ = 'possible dependence'.

3. *Demographic Pro-forma*

A Demographics Pro-forma was developed by the Researcher and contained five questions including: gender, age, ethnicity, marital status and employment status (Appendix H).

All measures were quick to self-administer. The SCI-R took on average five minutes to complete, the AUDIT less than two minutes, and the Demographics Pro-forma took two minutes to complete. All questionnaires could therefore be completed within ten minutes and it was felt that these measures were suitable to administer in the waiting rooms of busy Diabetes Clinic or GP surgery settings.

Procedure

Participant recruitment took place over a seven month period from October 2012 to April 2013 (see Appendix K for chronology of research process). Potential participants were identified through three sources, all accessing the NHS. Research Nurses identified individuals accessing a Specialist Diabetes Clinic, meeting the inclusion criteria, and mailed Participant Information Sheets (Appendix L) with a letter informing individuals that they may be approached to participate at their next appointment. Potential participants were then approached by the Researcher when they attended appointments and given questionnaire packs containing the Demographics Pro-forma, AUDIT and SCI-R. A covering letter was attached to the questionnaires asking for consent to (1) being contacted by the Researcher for Stage 2 and (2) for the Responsible Clinician (RC) in their care team being informed of their participation and results.

The second method of recruitment occurred by post and recruited from two sources. GP surgeries were recruited through the Primary Care Research Network (PCRN), chosen as they were deemed Research Site Initiative (RSI) level 2 practices that were highly experienced and motivated to engage in research. A member of the PCRN met with three surgeries initially to explain the purpose of the study and their involvement.

The three target practices included two within one Primary Care Trust (PCT). One practice held a patient list of approximately 5,000 and was based in an area considered middle class with a high proportion of South Asians; a second held a patient list of approximately 4,200 and was based in an affluent area with a high proportion of South East Asian ethnicity. One practice was recruited from a second PCT and held a patient list of

approximately 8,400, and was based within a predominantly white, economically deprived area. Practice Managers identified individuals meeting the inclusion criteria and were asked to randomly choose 200 participants through the use of 'MailMerge' random selection. Questionnaire packs containing the Demographic Pro-forma, AUDIT and SCI-R were mailed out, with a covering letter from the surgery and a return slip if participants consented to participate in Stage 2, with a pre-paid, self-addressed envelope for their return.

The second source of postal recruitment was the Diabetes Research Centre (DRC) research list. The Research Nurse identified those on the research list who met the inclusion criteria and had agreed to being contacted for questionnaire studies. Questionnaire packs containing the Demographic Pro-forma, AUDIT and SCI-R were mailed out, with a covering letter from the DRC and a return slip if participants consented to participate in Stage 2, with a pre-paid, self-addressed envelope for their return.

Consent to participate in Stage 1 was taken as implicit; a refusal to complete questionnaires was taken as a refusal to participate. Participants attending Diabetes Clinics were asked to hand questionnaires back to the Researcher following their appointments; GP surgery and Research List participants were asked to return questionnaires by post to an address at the local University where questionnaires were stored securely. A list of participant numbers was generated, with each recruitment point allocated a set of participant numbers. Research Nurses or Practice Managers allocated participant numbers to participants and stored the list of numbers securely at their practice or at the DRC. As a result, participants were only identifiable to their care team.

On receipt of completed questionnaires, the Researcher calculated the AUDIT score

and if participants scored 8 or above (indicating 'increasing risk', 'higher risk' or 'possible alcohol dependence') on the AUDIT and they had consented for their RC to be informed of their participation, their results were given to the RC to offer routine care such as referral on for support from local specialist alcohol services. If their results fell within the 'increasing risk' to 'higher risk' categories and consent had been given to being contacted for Stage 2, participants would then progress to Stage 2 of the study.

Data Collection

Questionnaires returned by post were collected at weekly intervals from the University address by the Researcher. Questionnaires obtained from Diabetes Clinics were stored securely at the Researcher's home address following completion. Data was extracted from the measures and inputted into a Statistical Package for the Social Sciences database (SPSS; Version 20) by the Researcher. All questionnaires were stored in a secure, locked cupboard at the Researcher's personal address, separate from any identifiable information.

Data analysis

Data analysis was conducted through use of SPSS software data analysis package. To answer Question 1 Chi squared test of goodness of fit was conducted to compare the number of individuals drinking at 'increasing risk' and 'higher risk' levels with estimates for the general population, therefore testing Hypothesis A: that measures of patterns of alcohol use would show numbers of 'increasing risk' to 'higher risk' drinkers similar to that of the

general population.

To examine Question 2 regarding the correlation between alcohol consumption and self-care behaviours Spearman's correlation was performed, which would allow exploration of Hypothesis B: that increased alcohol consumption would correlate with lower adherence to self-care behaviours. Analysis of variance (ANOVA) was performed to examine Hypothesis C: that older individuals would demonstrate better adherence to self-care behaviours. A t-test was performed to explore Hypothesis D: that females would score significantly less on the AUDIT than males.

Stage 2

Design

Stage 2 was a pilot study: a longitudinal, repeated measures design was utilised to assess changes in adherence to diabetes self-care behaviours and changes in alcohol use over time. A measure of these variables was taken at two points a month apart, to analyse change in alcohol consumption and adherence.

Participants

Sample Size

No a-priori power calculations were conducted as Stage 2 was a pilot study, therefore a small sample size was deemed appropriate. As limited research was available examining the intervention in this population, the number of participants required was based on a study by Ramsey *et al.* (2010), which compared BI and TAU groups, recruiting 14 participants to each group. It was estimated 20 participants for the pilot study would be sufficient to enable the Researcher to examine the efficacy of BI for this client group and consider the feasibility of its incorporation into routine care.

Identification of participants

Participants were identified from the results of the AUDIT screening from Stage 1. Twenty-one participants were eligible to take part in Stage 2, scoring between 8 and 19, and had consented to being contacted by the Researcher. Fifteen participants were not contactable, failed to attend appointments or withdrew consent, resulting in six participants recruited for Stage 2. Participant Information Sheets (Appendix M) were sent to provide further information about the study after which participants were contacted by the Researcher by telephone or letter to arrange a convenient appointment time.

Exclusion and Inclusion criteria

Inclusion criteria: Individuals were deemed suitable to include if they: scored between 8 and 19 (indicating 'increasing risk' to 'higher risk' drinkers) on the AUDIT screening tool; had a diagnosis of Type 2 diabetes; were over the age of 18 but under 75 years; attended

Specialist Diabetes Clinics or GP Surgeries; and were fluent/ had literacy skills in the English language sufficient to read Information Sheets, consent to participate and complete measures.

Exclusion criteria: Individuals were excluded if they: scored under 7 (indicating 'lower risk') or over 20 (indicating 'possible alcohol dependence') on the AUDIT; were under the age of 18 or over 75 years; were without a diagnosis of Type 2 diabetes; refused to or could not attend appointments; were lacking fluency/literacy skills in the English language; and lacked a capacity to consent.

Demographic Information

Of the six participants, five were male and 1 female; half fell within the 41-55 age bracket and the remainder into the >56 age bracket (see Appendix N for demographics table). All participants identified as White British, with four married and two co-habiting. Four of the six were retired and two in full-time employment. Generalisability of results was not considered due to the small sample size, and as this was a pilot study. Most demographic variables fit with the representation presented in Stage 1, however increased variety in ethnicity and better equality of gender representation would have been preferable.

Materials

Materials used for delivery of the BI included a BI Pack, in line with NICE guidelines (2010) containing information on how to deliver a BI, a visual presentation to enable comparison of participants' alcohol consumption with the national average

consumption levels and tips on how to reduce alcohol consumption for participants to keep

(a Handout and Unit Calculators; see Appendix O for example BI pack). These materials

were obtained from the Department Of Health and drinkaware (drinkaware, 2011;

Department of Health, 2011). A handout was also put together of local service provision

and useful numbers for further support (Appendix O).

Measures

Measures were previously reported in Stage 1. All measures were quick to

self-administer. The SCI-R took on average five minutes to complete, the AUDIT less than

two minutes, and the Demographics Pro-forma took two minutes to complete. All

questionnaires could therefore be completed within ten minutes.

Procedure

As originally envisaged the Brief Intervention would be conducted by staff

immediately following completion of the stage 1 of the study, however due to feasibility

issues the procedure was altered.

Following scoring of the returned questionnaire packs from Stage 1 the Researcher

contacted six participants who had scored between 8 and 19 on the AUDIT, had consented

to being contacted and provided contact details on a return slip. Twenty-one participants

fell within the inclusion criteria and agreed to be contacted. Fifteen had consented to be

contacted but were then un-contactable as they failed to answer their phone on three

occasions, withdrew consent, could not attend appointments between the hours of 9-6 or

did not attend arranged appointments. Due to the low numbers eligible and consenting to participate in Stage 2, all participants who were eligible were asked to participate.

The Researcher sent letters by post to participants' home addresses containing a Participant Information Sheet (Appendix M) outlining the study, a covering letter including a University phone number, and Researcher's email address for any queries. Participants were then contacted by phone or letter to arrange a BI appointment. At the commencement of the appointment the Researcher answered any questions about the study. It was kept in mind that participants may have felt pressurised to participate due to concerns about participation refusal impacting upon care. It was therefore clearly stated that the study was being conducted independently by a Researcher at the University of Leicester.

At the commencement of BI appointments a Consent Form was provided (Appendix P) which stated that participation was voluntary. Once written consent was gained, participants were asked to complete the SCI-R, AUDIT and Demographic Pro-forma once again. The Researcher then performed a 5-15 minute BI, utilised the BI pack containing leaflets regarding safe drinking practices, a visual aid and unit calculators (Appendix O). The BI followed the FRAMES principles (NICE, 2010) by providing participants with feedback on their pattern of alcohol use, encouraging responsibility taking, providing limited advice regarding alcohol and it's risks, providing a menu of options to support reduction to within safe levels, expressing empathy and encouraging self-efficacy. This was based on the principles and practice of MI (Miller & Rollnick 2002), of which the Researcher had received prior training.

Following the BI, participants were given blank copies of the AUDIT and SCI-R to complete and return by post a month later to measures changes in alcohol use (frequency or overall level) or changes in adherence to self-care behaviours in the month following base-

line measure. They were provided with a pre-paid envelope addressed to the Researcher at the University, for ease of return. Participants were also offered a re-imbursement of up to £10 for travel expenses.

Data Collection

The Researcher stored questionnaire data securely in a locked cabinet at a personal address following baseline appointments and separate from any identifiable information. Follow-up measures were stored securely at the University until collected by the Researcher. Collected data was inputted into a SPSS database by the Researcher.

Data analysis

Data analysis was conducted through use of a SPSS analysis package. Part of Question 1, regarding the efficacy of BIs on alcohol consumption was analysed using descriptive statistics. Following this, a Wilcoxon Sign Rank Test analysed changes in alcohol usage and adherence to self-care behaviours between base-line and follow-up, addressing Hypothesis E: that following a BI for alcohol participants would see a reduction in AUDIT scores at one month follow-up. Following this, Hypothesis F: that a reduction in AUDIT score at one month follow-up would correlate with increased self-care was examined through applying Spearman's Rank Order Correlation (rho).

Results

Data preparation

      A codebook was generated to assign codes to each item and each possible answer. The answers to each item were then inputted into SPSS Version 20. Data cleansing was conducted, checking data entries for errors and missing data. Participants failing to complete all questions on the AUDIT, or eleven or more questions on the SCI-R were removed prior to analysis.

Stage 1

      The first stage of the study aimed to identify the prevalence of 'increasing risk' to 'higher risk' drinkers according to the AUDIT, and the relationship between alcohol use, demographic variables and adherence to self care behaviours. The chi-squared test for goodness of fit was conducted to compare the percentage of the sample falling within 'increasing risk' and 'higher risk' categories with estimated figures for the East Midlands. Spearman's rho correlation analysis was used to examine the correlation between alcohol consumption and adherence to self care behaviours. Analysis of variance was conducted to assess difference in adherence across age groups, and a t-test was utilised to examine difference in AUDIT scoring between genders.

      Missing data rendered 97 participants' results ineligible for inclusion. As total scores were required for both the SCI-R and AUDIT participants who had failed to complete items were not included in analysis; with the exclusion of individuals who failed

to complete items 3, 13 and 15 on the SCI-R (as it was recommended these were not included in calculations; Bentler, 1990) and/or failed to complete more than eleven items (the SCI-R with less than 11 items completed is not considered a reliable or valid measure; Khangram *et al.,* 2013). No participants included in the analysis had missing data for any variable or measure.

Achieved Sample

Recruitment commenced in October 2012, until April 2013. In total 19 Diabetes Clinics were attended, with an average of 36-37 potential participants attending each clinic. The Diabetes Research Centre mailed out questionnaire packs to individuals on their Research List and consenting to be contacted for questionnaire based research in November 2012. In February/March 2013, three GP surgeries mailed out questionnaire packs, each to 200 Type 2 diabetic individuals held on their patient lists, chosen at random.

A total of 698 individuals attending the Diabetes Clinic were examined for eligibility, and of these, 225 were identified as eligible, with 119 completed measures (see Appendix K for diagram of attrition rate and reasons for inclusion/exclusion). A total of 172 individuals on Diabetes Centre Research List and approximately 17,600 individuals attending the three GP surgeries were examined for eligibility. Of these, 694 individuals were sent questionnaire packs (600 from GP surgeries and 94 from the Research List) and 160 returned completed measures. A total sample of 279 therefore participated in Stage 1 of the study and 182 participant results were included in analysis. Reasons for exclusion of participant data from analysis included 49 participants failing to complete the AUDIT, and

as a total score was required their data was ineligible for use; 48 participants failed to complete more than 11 items of the SCI-R, which was considered to lack reliability and validity if less than 11 items were completed (Khagram *et al.,* 2013).

In total 182 participants were included in the analysis for Stage 1 of the study. This did not meet a-priori power analysis, which included a 95% confidence interval, an error probability of 0.5 and predicted total sample size of 255 participants to enable an estimation of alcohol consumption to be made, with sufficient statistical power. Adjusting of power calculations indicated that the sample size met power analysis with an error probability of 0.1, although not ideal, this did allow for a level of confidence regarding findings.

Demographics

The sample consisted of 41.8% females (see Appendix J for demographics table separated according to recruitment source), 71.4% falling within the >56 years age bracket (71.4%); 22.5% in the 41-55 years age bracket and 6% in the 26-40 years age grouping. Of the participants, 69.2% self-identified as White British, with 24.7% identifying as Asian Indian, with the remainder identifying as Pakistani, any other Indian background, Caribbean, African and any other White background. Most participants identified as married (65.9%) and nearly half of all participants identified as retired (46.7%), with 30.8% in full-time employment, 6% in part time employment, 5.5% self-employed and 8.2% unemployed or unable to work. As previously mentioned, the sample was in line with age and gender estimates of the Type 2 diabetic population, but failed to represent the estimated increased prevalence in certain ethnic groupings.

Self Care Inventory Revised (SCI-R)

A number of items on the SCI-R were not completed by participants; if participants completed less than 11 items an overall score on the SCI-R could not be calculated. If 11 questions were not completed participants were therefore excluded from analysis. If participants completed 11 or more questions, items that failed to be completed were not included in the calculation of SCI-R total. Of the total sample, 17% failed to complete the measure sufficiently for inclusion.

Statistical and reliability analysis for the SCI-R revealed a Cronbach alpha coefficient of .617, which was below the suggested ideal of .7 (DeVellis, 2003). However, if item 12 was removed, Cronbach's alpha increased to .751, indicating good internal consistency. This suggested that item 12, regarding attending clinic appointments did not give a measure of self-care, in line with other measure items. A UK based study by Khagram *et al.* (2013) reported the SCI-R to have good internal consistency, with a Cronbach alpha coefficient reported of .77. The lower internal consistency reported in the current study may be the result of smaller sampling sizes or differing sampling sources.

Descriptive statistics for the SCI-R are reported in Appendix Q. Mean SCI-R score for each question across the sample was 3.39 out of a possible maximum score of 5 (s.d. 0.60996). Mean scores ranged between 2 and 4.83. Mean total score on the 0-100 point scale was 59.85 (s.d. 15.193), ranging between 25 and 96. A histogram of the total score distribution suggested normal distribution of scores (Appendix R). Assessment of normality of distribution indicated that data was normality distributed (Kolmogorov-Smirnov statistic of .042, p=.20).

Alcohol Use Disorders Identification Test (AUDIT)

A number of participants failed to complete items on the AUDIT. As an overall score was required, calculated from all items, participants who had not completed all items on the AUDIT were excluded from analysis. Of the total sample, 14% failed to complete the measure sufficiently due to an error in the questionnaire pack, and a further 4% failed to complete the measure sufficiently for inclusion. When preparing the measure for reliability analysis, two items (4 and 5) were reverse scored due to their negative wording of questions (Pallant, 2011). Statistical and reliability analysis for the AUDIT revealed a Cronbach alpha coefficient of .708, suggestive of good internal validity. This was in line with the WHO document '*The Alcohol Use Identification Test: Guidance for use in Primary Care'* (Barbor *et al.,* 2001) which reviewed relevant research and reported the AUDIT to have high internal validity.

Descriptive statistics for the AUDIT are reported in Appendix Q. The mean AUDIT score across the sample was 2.7 (s.d. 3.322), with a minimum score of 0 and a maximum of 17. A histogram of the total score distribution suggested scores were not distributed normally, with most scores skewed to the left (Appendix R). Assessment of normality of distribution indicated a violation of the assumptions of normality (Kolmogorov-Smirnov statistic of .208, p=.0001), which may reflect the prevalence of alcohol use. This was however in line with estimates for AUDIT scoring across the East Midlands, as 79% of the population are suggested to be drinking within safe levels (as indicated by a lower AUDIT score; Alcohol Concern Alcohol Harm Map, n.d.).

Question 1

What percentage of those with Type 2 diabetes are using alcohol to 'increasing risk' to 'higher risk' levels according to the AUDIT?

Chi-squared test for goodness of fit was performed as this would allow for the proportion of cases in the sample falling within 'increasing risk' to 'higher risk' categories on the AUDIT to be compared to estimates of the general population. The data met the assumptions of this test as the sample was random and the observations independent. The achieved sample provided 90% confidence interval for the analysis. The chi-square test of goodness of fit results indicated a significant difference in the proportion of individuals consuming 'increasing risk' to 'higher risk' levels of alcohol according to the AUDIT in the current sample (8.79%) in comparison with the population in the East Midlands, estimated at 21% (obtained from the Alcohol Concern Alcohol Harm Map, n.d.), χ^2 (1,n=182) =16.35, p<.001 (see Appendix S for analysis results). Therefore Hypothesis A: that numbers of 'increasing risk' to 'higher risk' drinkers according to the AUDIT would be similar to that of the general population was not supported.

Question 2

What is the correlation between alcohol consumption and adherence to self care behaviours?

The correlation between scoring on the alcohol screening and self-care measures were examined in a scatter plot (Figure 1.) which demonstrated an increase in AUDIT

scores to correlate with a reduction in SCI-R scores. The correlation between alcohol

consumption and self-care was examined through applying Spearman's correlation.

Spearman's correlation was utilised as it allowed for the exploration of the relationship

between two independent variables: alcohol consumption and self-care (as measured by the

AUDIT and SCI-R). This form of analysis was conducted as the assumptions of the

parametric alternative, Pearson's correlation, were not met: specifically the assumptions of

homoscedasticity and normality of distribution of data. Results demonstrated a small,

negative correlation between alcohol consumption and adherence to self-care, r= -.275,

n=182, p<.01, with higher scores on the AUDIT alcohol screening tool associated with

lower scores on the adherence to self-care measure (Appendix T). Scores on the AUDIT

helped to explain 7.6% of the scores in self-care. Therefore Hypothesis B: that increased

levels of alcohol consumption would correlate with lower adherence to self-care behaviours

was supported.

Figure 1. The correlation between alcohol screening tool (AUDIT) score and adherence to self-care (SCI-R) score
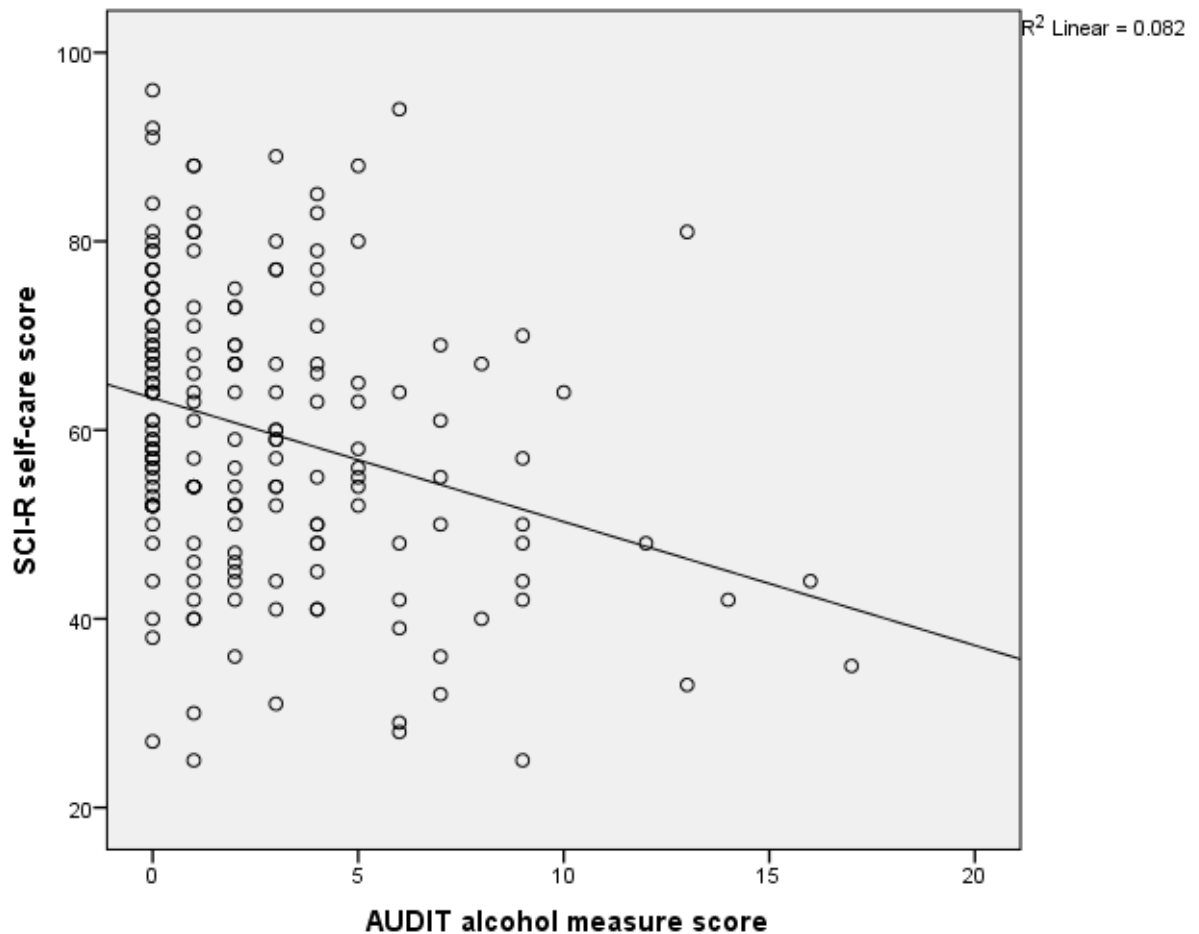
The impact of age on adherence to self-care, as measured by SCI-R was explored using a correlation graph and an independent groups design analysis of variance (ANOVA) with SCI-R score as the dependent variable. The assumptions of the ANOVA were met as the dependent variable had a continuous scale, scores were obtained from a random sample and observations were independent of one another. Scores were not normally distributed, however as the sample was large it was considered that violation of this sample should not

result in difficulties (Pallant, 2010). The correlation graph displayed in Figure 2. demonstrate mean total SCI-R score to increase with age, dipping within the 41-55 years age group. Of interest, mean AUDIT score displayed in Figure 3. presents an inversely comparable pattern. Descriptive analysis revealed a mean SCI-R score for the 26-40 years age group of 59 (s.d.6.53), a mean score of 57.17 (s.d.15.98) for the 41-55 years age group and a mean score of 60.77 (s.d.15.435) for the >56 years age group.

The ANOVA was used to explore whether significant differences in mean SCI-R scores existed across the three age groups (26-40, 41-55 and >56; the <25 years age group was removed as no participants fell within this category). The significance level for Levene's test was 3.531, therefore did not violate assumption of homogeneity of variance. Results revealed no statistical significance at the $p<.05$ level with 95% confidence interval on mean SCI-R scores between age groups ($p<.412$; Appendix U). Therefore Hypothesis C: that older individuals would demonstrate better adherence according to the SCI-R was not supported. Post-hoc analysis was therefore not conducted.

The possibility of Type 2 error was considered as the non-significant result may have been obtained due to lack of power, as two of the groups consisted of small numbers of individuals. When the alpha level was adjusted to 0.1 to compensate for the small numbers in two of the groups it still remained that there was no statistical significance between groups.

Figure 2. Mean SCI-R total scoring according to age group
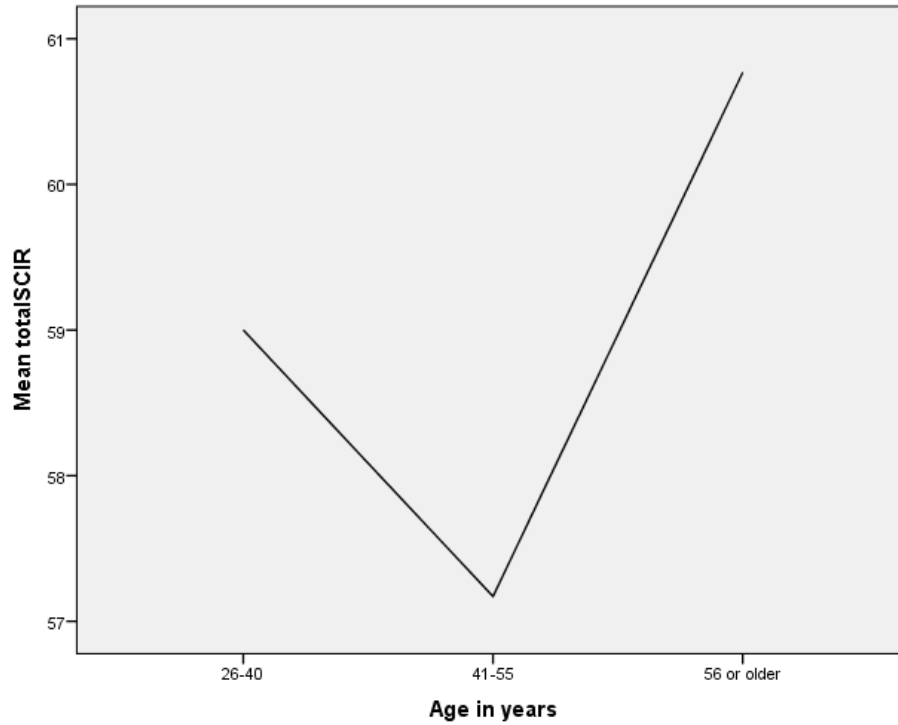
Figure 3. Mean total AUDIT scoring according to age group
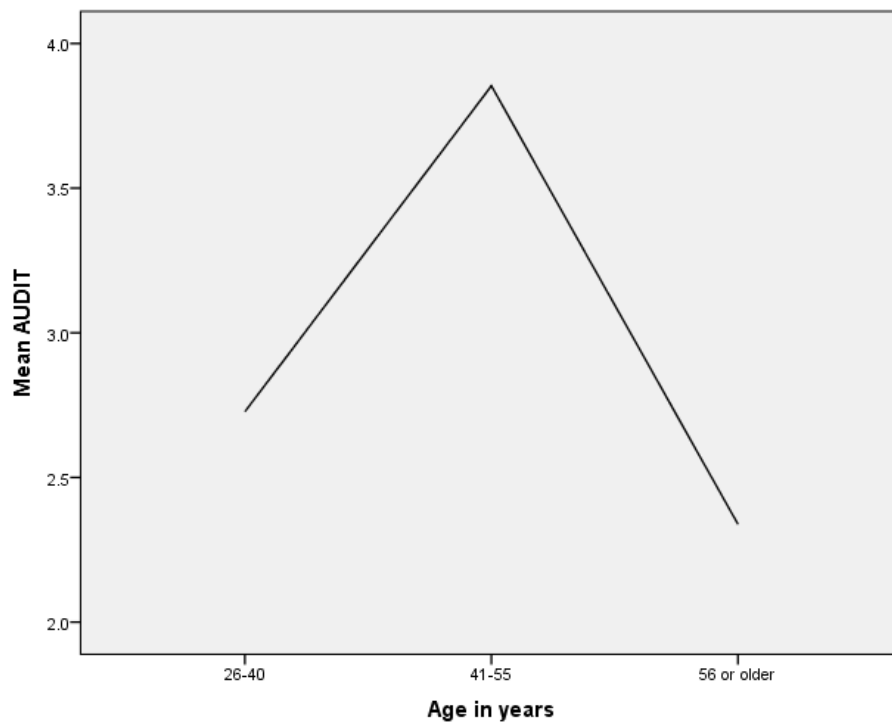
An independent samples t-test was performed to explore Hypothesis D: that females would score significantly less on the AUDIT. A t-test was used as it would allow for comparison of AUDIT mean scores between males and females (Appendix V) and as the assumptions for this analysis were met, including independence of observations, random sampling, and as the AUDIT was a continuous measure. Scores were not normally distributed, however due to large sample size it was not foreseen that this would cause difficulties (Pallant, 2010). As analysis revealed the variance between the groups was not equal, results provided for when assumptions were violated were utilised.

Results revealed a significant difference in AUDIT scores for females (M=1.64, SD=2.183) and males (M=3.47, SD=3.789); t (178)= 4.070, p<.001, two tailed at 95% confidence interval. The effect size of the difference was calculated (mean difference =1.826, 95% CI:0.940-2.712) and a moderate effect size was revealed (eta squared= .085). Therefore the percentage of the variance in AUDIT score explained by gender was 8.5%, with females reportedly scoring less than males on the AUDIT.

Stage 2

The second stage of the study aimed to identify whether a BI targeting 'increasing risk' to 'higher risk' drinking would bring alcohol consumption within 'safe limits' and as a result, increase adherence to self-care behaviours in those with Type 2 diabetes. Descriptive statistics were used to give a preliminary estimate of pre- and post- mean SCI-

R and AUDIT scores.

The Wilcoxon Sign Rank Test was used to examine the impact of BIs on AUDIT score and adherence to diabetes self-care behaviours; the impact of BIs on self-care were then analysed using Spearman's Rank Order Correlation (rho).

The Wilcoxon Sign Rank test was used as it examined changes in the same participants' scores over time, and as the sample did not meet the assumptions of the parametric alternative, the paired-samples t-test, and was the test was suitable for use with a repeated measures design. The less stringent assumptions of the Wilcoxon Sign Rank test were met including the use of an ordinal measure, utilising paired samples from the same population and that pairs were chosen randomly. The Spearman's Rank Order Correlation was used as it would allow examination of the strength and direction of the relationship between AUDIT and SCI-R scores. Preliminary analysis revealed that data did not meet the assumptions of Pearson's Correlation Coefficient (the parametric alternative) as data distribution violated assumptions of linearity and homoscedasticity (Appendix R for graphs), but met the less stringent assumptions of the Spearman's Rank Order Correlation, including the use of an ordinal measure and a monotonic relationship between variables.

Data was extracted from questionnaires and entered into SPSS. No participants included in the analysis had missing data for any variable.

Achieved sample

Recruitment for Stage 2 of the research began at the commencement of recruitment

for Stage 1 and continued until March 2013. The first individual was recruited in January 2013. Six individuals were recruited to Stage 2, of a possible 21. Fifteen participants were not recruited as five were not contactable, two did not attend the BI appointment and eight participated in Stage 1 after March 2013, which would not allow sufficient time to gather follow-up data. Six participants were therefore recruited to Stage 2 of the study; all completed follow-up measures and were included in analysis (see Appendix K).

Demographics

A majority male sample was recruited, with only one female of the six participants. Half of the sample fell within the 41-55 years age bracket and the remainder into the >56 years age bracket (see Appendix N for demographics table). All participants identified as White British, with four married and two co-habiting. Four of the six were retired and two were in full-time employment.

Question 3

'What impact will BIs for alcohol have on patterns of alcohol use and adherence to diabetes self-care behaviours?'

The Wilcoxon Signed Rank test was used to examine the impact of BIs for alcohol on patterns of alcohol use and adherence to diabetes self-care behaviours. Descriptive statistics allowed preliminary examination of pre and post AUDIT mean scores and total SCI-R scores. The median scoring on the AUDIT decreased from 14 to 11 following BI,

which suggested consuming alcohol to safer levels.

The Wilcoxon Signed Rank test revealed that the difference between AUDIT scores at baseline and follow-up were not statistically significant, z=-1.160, p<.138, calculated at 95% confidence interval, with a large effect size (r=.82)(effect sizes as advised in Cohen, 1988; see Appendix W for test results). Therefore Hypothesis E: that following the BI, participants would demonstrate a reduction in AUDIT scores at one month follow-up was not supported.

The impact of BIs on self-care behaviours was analysed using Spearman's Rank Order Correlation. The relationship between self-care (as measured by the SCI-R) and pattern of alcohol use (as measured by the AUDIT) revealed a strong, inverse correlation between these measures taken at baseline, rho=-.759, n=6, p=.08, significant to 90% confidence interval. Lower scores on the AUDIT were associated with higher scores on the SCI-R, with AUDIT scores helping to explain 57% of the variance in SCI-R scores. The relationship between self-care and pattern of alcohol use revealed a weak, statistically insignificant negative correlation between these measures taken at follow-up, rho=-.086, n=6, p=.872. With lower scores on the SCI-R associated with higher scores on the AUDIT. Therefore Hypothesis F: that a reduction in AUDIT score at one month follow-up would correlate with increased adherence to diabetes self-care behaviours was not supported, however lower AUDIT scores at baseline did significantly correlate with higher levels of self-care.

Discussion

The current study addressed the gap in knowledge regarding the prevalence of alcohol use of those with Type 2 diabetes, whether this correlated with adherence to self-care, and if Brief alcohol Interventions (BI) would reduce alcohol consumption and increase adherence to diabetes self-care.

A quantitative approach was taken with a cross-sectional correlational design utilised to examine the prevalence of alcohol use and its relationship with diabetes self-care in the first stage of the study, followed by a repeated measures pilot study to examine the efficacy of BIs for alcohol in reducing alcohol intake and its impact on self-care. The second stage however suffered feasibility issues that saw the Researcher conduct the BI's rather than healthcare professionals, therefore the feasibility of including BIs in routine care remains unknown. The pilot study also only recruited six participants; with this knowledge a qualitative approach would have produced a greater richness of data and may have been the best approach in hindsight.

The sample was recruited from three GP surgeries, a Diabetes Clinic and a Diabetes Centre Research List, with approximately 18,470 individuals screened for eligibility from across three Primary Care Trusts. Although representative of the Type 2 diabetic population with a higher proportion of males (58.2%) and most over the age of 56 years of age (71.4%), the sample was unexpectedly lacking in ethnic diversity, with 69.2% identifying as White British. The exclusion of non-English speakers from participation may have contributed to this.

Mean score on the measure of self-care (the SCI-R) was reported as 60/100 which was

in line with levels of adherence suggested in previous literature, with a prior study of 353

individuals revealing an average score of 69/100 (Khagram *et al.,* 2013). It was considered

however that the current findings regarding adherence to self-care could be biased due to the

sample accessed, as the current sample were demonstrating adherence in the very nature of

their attendance of diabetes check-up appointments and motivation to take part in research.

The previous study also recruited those already participating in research. The sample achieved

therefore may have displayed higher self-care than those failing to attend appointments or not

registered with a GP.

A certain level of diabetes related knowledge was presumed with regards to

completing measures, however 48 of 279 individuals failed to complete all items on both

measures, which may have resulted from a lack of health literacy or diabetes knowledge; some

questions on the SCI-R required further explanation from the Researcher by those attending

the Diabetes Clinic on a number of occasions. This was in contrast to a 95% completion rate

for the SCI-R reported in Khagram *et al.* (2013); however the sample was obtained from

participants of a clinical trial, and therefore those taking part were postulated to have good

levels of knowledge regarding diabetes, self-care and complications.

Prevalence of alcohol use

The prevalence of 'increasing risk' to 'higher risk' drinkers in the current sample was

not in line with the general population: only 9% of the sample population reported to be

consuming alcohol at this level in comparison with an estimated 21% of the East Midlands

population (Alcohol Concern Alcohol Harm Map, n.d.). Therefore Hypothesis A: that

measures of alcohol use would show numbers of 'increasing risk' to 'higher risk' drinkers

similar to that of the general population was not supported.

Prior research examining the prevalence of alcohol consumption in the Type 2 diabetic population had not been conducted and therefore it could only be speculated as to the difference in prevalence in comparison with the general population. It was considered that as individuals consuming higher levels of alcohol are more likely to demonstrate decreased levels of motivation to adhere to self-care (Ahmed *et al.*, 2006), they may have failed to attend appointments or to return the questionnaires and therefore not participated in the current study, resulting in an underestimation of those drinking at 'increasing risk' and 'higher risk' levels. It was also considered that participants could be under-reporting alcohol use due to social desirability or that participants could have reduced alcohol consumption already following diabetes diagnosis.

To note however, 9% of the Type 2 diabetic population could be of clinical concern, consuming alcohol at 'increased risk' and 'higher risk' levels, and therefore at increased risk of both alcohol-related complications and diabetes-related complications associated with alcohol consumption. Furthermore it is proposed that professionals who are unaware of their patients' alcohol use may be unable to successfully support self-management (Howard *et al.,* 2004). Therefore, despite the percentage of the current sample drinking at 'increasing risk' and 'higher risk' levels measuring 9% it remains the case that this provides justification for the provision of screening and support regarding alcohol in the Type 2 diabetic population.

Demographic variables, adherence and alcohol consumption

A small, negative correlation was reported between scores on the alcohol screening tool (AUDIT) and scores on the adherence to self-care measure (SCI-R), with higher scores on the alcohol screening tool associated with lower scores on the adherence to self-care measure. Therefore Hypothesis B: that increased levels of alcohol consumption would correlate with lower adherence to self-care behaviours, was supported. Findings were consonant with previous literature that has reported alcohol use to reduce motivation to adhere to self-care (Ahmed et *al.,* 2006). Clinical implications include the importance of introducing routine screening of individuals for alcohol use to identify this risk factor for low adherence to self-care.

A relationship between older age groups and improved adherence to self-care was not found in the current study. Therefore Hypothesis C: that individuals within the older age groupings would demonstrate better adherence to self-care behaviours than those within the younger age groupings, was not supported. This non-significant finding may have resulted from a lack of power in the analysis as two of the age groups consisted of small numbers of individuals. Findings related to age were not in line with a previous review which reported increased age to correlate with higher self-care adherence (Peeters *et al.,* 2010). However it was also reported by Peeters *et al.* (2010) that adherence rates declined for the oldest of age groups, but they failed to define 'oldest age groups' in terms of years old. If the current study had provided an increased number of age groups in the Demographics Pro-forma this may have resulted in similar findings.

A significant difference in the alcohol screening measure score was revealed, with

females scoring on average nearly two points lower (M=1.64) than males (M=3.47),

therefore Hypothesis D: that females would score significantly less than males on the

alcohol screening tool, was supported. The gender difference concurred with previous

literature: 18% of females in the general population, in comparison with 26% of males, to

be consuming over recommended government guidelines for alcohol use (Office for

National Statistics, 2009). Clinical implications include increased awareness of

professionals working in diabetes care of the gender inequalities that shows an increased

risk of males consuming over recommended levels of alcohol, and thus being potentially at

risk of reduced adherence to diabetes self-care.

Alcohol use and adherence to self-care

In the second stage of the current study, the pilot phase, a strong correlation was

revealed between high alcohol screening tool scores and low adherence to self-care scores

taken at baseline, indicating higher levels of alcohol use correlated with lower adherence to

self-care. Previous literature has documented reduced adherence with increased levels of

alcohol use (Ramsey *et al.,* 2010). However, due to the small sample size results had

limited clinical implications.

Brief Interventions for alcohol

In the second stage of the current study it was observed that the median alcohol

screening tool score decreased from 14 to 11 following Brief Intervention (BI), which

suggested either a reduction in alcohol consumption or a safer pattern of consumption. No

participants moved from 'increasing/higher risk' into the 'lower risk' category which was

unsurprising given the short time period between base-line and follow-up. Despite a large

effect size being reported, the difference between AUDIT scores at baseline and follow-up were not statistically significant; less of a concern given that this was a pilot study. Therefore Hypothesis E: that following a BI for alcohol, participants would see a reduction in their AUDIT scores at one month follow-up, was not supported.

A previous study by Ramsey *et al.* (2010) revealed a significant reduction in alcohol consumption following BI in comparison with a TAU group; however the effect was observed six months post-intervention. It may be that with a larger sample size and longer time between base-line and follow-up a greater effect may have been observed.

A significant amount of research suggests that an individual's readiness to change may contribute towards the efficacy of BIs (Prochaska & Diclemente's Stage of Change Model, 1983; Prochaska *et al.,* 1992). Time since diagnosis was not recorded in the current study. However a number of participants reported being diagnosed within the past five years and not having come to terms with their diagnosis; they therefore may have not been ready to consider change in behaviour such as a reduction in alcohol consumption.

The increase in median score on the adherence to self-care measure from 45 to 59 following the BI in the pilot study suggested improved adherence to self-care. Further analysis revealed a weak negative correlation between alcohol screening tool score and adherence to self-care measure score taken at follow-up, with lower adherence to self-care associated with higher scores on the alcohol screening tool. The difference was not statistically significant; however as this was a pilot study this was of less concern. Therefore Hypothesis F: that a reduction in AUDIT score at one month follow-up would correlate with increased adherence to diabetes self-care behaviours was not supported.

Prior research in the USA (Ramsey *et al.,* 2010) revealed a correlation between reduced alcohol consumption and improved adherence to certain components of self-care following a BI. This suggests that the findings of the current study justify future RCTs examine the efficacy and feasibility of the inclusion of BIs into routine diabetes care in the UK.

The current study's contribution to the research area

Previous research has focused upon alcohol as a risk factor for diabetes or the impact of alcohol on biological aspects of diabetes. The current study provides invaluable information regarding the prevalence of alcohol consumption in this population, the impact of alcohol on adherence to self-care and the potential benefits of provision for screening and BIs for alcohol as part of routine diabetes care. Little prior literature had examined the prevalence of alcohol use in a sample of those with Type 2 diabetes, therefore comparison of findings with earlier research was not possible. Similar studies examining the impact of alcohol on adherence to self-care and the efficacy of BIs in this population supported the findings of the current study (Fleming *et al.,* 2004; Ramsey *et al.,* 2010). The current study served to address the gap in knowledge regarding the prevalence of alcohol use in the UK population and provides validation for future RCTs to further examine the efficacy of BIs in reducing alcohol consumption and improving adherence to diabetes self-care.

The current study provides useful considerations for clinicians working within UK diabetes care as it highlights alcohol as a factor impacting on adherence to self-care. On the strength of the current results, screening for alcohol use should be considered for

integration into routine diabetes care, particularly as at least 9% of the population is drinking at 'increasing risk' or 'higher risk' levels. This is particularly warranted due to the increased risks associated with alcohol consumption in this population. Support should be targeted at males, with the knowledge that males score higher on the AUDIT, indicative of more risky patterns of alcohol consumption. A screening tool for alcohol use should provide indications for clinicians regarding individuals at risk of demonstrating low adherence to diabetes self-care.

Limitations

The limitations imposed by the current research design included the lack of causal relationships that could be inferred. Limitations were also imposed by the sample size, as it was estimated that 255 participants were required for the first stage of the research to minimise the error level to 0.05. Although not ideal and as a result of recruitment difficulties this number of participants could not be recruited; however an error probability level of 0.1 was met. Due to the smaller than preferred sample size, statistical significance of results was reduced, however clinical significance remained.

A longitudinal design with a larger sample size would have been an alternative and preferred approach to address the questions regarding prevalence and correlations between alcohol consumption and self-care. An RCT with a larger sample size and a longer follow-up period to explore the efficacy of BIs in reducing alcohol consumption and improving adherence would have been preferable.

The provision of the alcohol intervention by a Doctoral level Clinical Psychologist again limited the exploration of the feasibility of inclusion of BIs in routine diabetes care and to truly evaluate the efficacy of opportunistic BIs as advised by Barbor *et al.* (2001). The current study was unable to recruit staff to screen for alcohol use and provide BIs. Future research should engage staff working within routine diabetes care to assess alcohol use and provide BIs opportunistically, possibly through the provision of protected time to do so, or financial or target driven incentives. This recommendation is supported by Engler *et al. (*2010), with Fleming *et al.* (2004) suggesting the training of one or two nursing staff within each diabetes clinic to provide BIs for alcohol for those identified as 'risky' drinkers. This would also allow for the specialist knowledge of clinicians working routinely in this setting to adapt the BIs according to the need of the population.

In the current study, the impact of a number of confounding variables suggested to impact on adherence to self-care could not be measured or controlled for. For example, the literature suggests social support (Schiotz *et al.,* 2011), depression (Egede *et al.*, 2009) and self-efficacy (Nelson *et al.*, 2007) to impact adherence to self-care. However due to the complexity of measuring these concepts and the requirement of the clinics that measures be quick to complete, these factors were not be included in the current study.

The current measures utilised had limitations, particularly the reliance on self report. Self-report does have suggested reliability when examining for example, medication adherence (Bodenheimer *et al.,* 2002). However reliability of findings may have been further improved by accessing medical files for biological measures, such as most recent blood sugar measure, or records of attendance at appointments.

The measure used to examine adherence to self-care may have imposed limitations. WHO (2003) advise the independent assessment of adherence to each component of the self-care over the use of a single measure to assess overall adherence. This relates to the weak correlation between separate self-care behaviours, suggesting adherence to be a multi-dimensional construct. The measure used in the current study may have therefore attempted to over-simplify the construct of adherence. The SCI-R had, however, been found to have sufficient validity for use in this population (Weinger *et al.,* 2005; Khangram *et al.,* 2013) and was considered easy to use, low cost, validated, and to give clear evidence of the degree of adherence to specific activities in diabetes self-management, suggested to be the components of a good measure (Hearnshaw & Lindenmeyer, 2005). The use of the AUDIT in the pilot study to measure change in alcohol consumption was not ideal, as the measure is a screening tool rather than an outcome measure. Preferable, alternative measures may have included recording days drinking/units per day.

The method of recruitment employed for the study may have imposed limitations. Those attending GP surgeries, Diabetes Clinics and registered with the DRC research list were already demonstrating some level of adherence by the very nature of attending appointments and willingness to engage in research. This may have biased results, as those demonstrating poor adherence to attending regular diabetes appointments were not accessed.

Generalisability of the current findings should be considered; due to time and resource constraints, those who did not access Diabetes Clinics or GP surgeries were not recruited, and those unable speak or write in English were excluded. This therefore may have resulted in the biasing of results.

Future Research

Future research should include qualitative studies, including focus groups with patients and staff. This would provide an indicator of the perception of the need for, and any barriers to introducing BIs for alcohol into routine care. Longitudinal studies and RCTs should be conducted with larger cohorts and control groups to examine the feasibility of training clinicians to include opportunistic BIs within routine diabetes care and the efficacy of BIs in reducing alcohol use and improving self-care.

Future research should also attempt to recruit those not attending routine diabetes care, for instance, by recruiting those attending general healthcare settings, those with diabetes accessing A&E services as the result of poorly controlled diabetes resulting from alcohol consumption or those accessing alcohol support services. Future studies should also include the non-English speaking population, due to the high incidence of diabetes in certain ethnicities (The Information Centre, 2006).

'Readiness to Change' (Prochaska *et al.,* 1992) should be assessed in future research as it is purposed to impact on the efficacy of any intervention; and more complex assessments of adherence should be conducted, including taking biological measures to improve reliability of self-report.

Conclusion

In conclusion, the current findings have important clinical implications, with 9% of those within the sample population drinking at 'increasing risk' to 'higher risk' levels so putting themselves at risk of reduced adherence to self-care and increased risk of complications. In addition higher levels of alcohol use correlating with lower adherence to self-care revealed in the current study therefore suggesting the integration of an alcohol use screening tool into routine diabetes assessment may be beneficial, particularly as lower adherence to diabetes self-care with increased alcohol consumption was found in the current study and in prior literature. Training may also support clinicians to identify individuals who are at risk of not adhering to self-care, such as males being at higher risk of 'risky' alcohol consumption, thereby enabling them to put in place interventions or increased support to improve adherence and reduce the risk of diabetes-related complications.

The implementation of screening and BIs should improve effectiveness of current diabetes care on offer, reduce alcohol-related complications, and quite possibly reduce the risk of diabetes-related complications. This has implications for the long-term management of the disorder, with improved outcomes predicted, as well as financial implications for services due to reduced need for treatment of complications or inpatient care.

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Critical Appraisal

Literature review

    The literature review retained a focus on psychosocial factors more amenable to change due to clinical relevance, and demographic factors such as age and gender, were not addressed. Increased awareness of these factors, may have resulted in the inclusion of more questions in the Demographic Pro-forma, to enable their inclusion in the analysis. The number of factors possible to include however would have been limited as the measure was required to be short and quick to complete.

    The literature review focused upon quantitative literature, however reading of qualitative literature provided a useful grounding for conducting the research due to an increased understanding of the experience of living with diabetes and the difficulties specific to this chronic disorder.

    The STrength of the Reporting of OBservational studies in Epidemiology (STROBE; STROBE website, 2009) was utilised to assess quality of reporting of articles. This tool was chosen as it was endorsed by over 100 journals (STROBE statement). Guidance in the use of this tool was sought from the STROBE explanatory article (Vandenbrouke *et al.,* 2007). No specific recommendations were made regarding a cut off point to indicate what constituted poor vs. adequate/good quality of reporting, however, it was felt that articles failing to meet 14+ checklist items were reporting insufficiently to allow for studies to be scrutinised for methodological weaknesses. Articles scoring less than 14 were therefore excluded.

Development of the research questions

My interest in the interaction between diabetes and alcohol began whilst working as an Alcohol Liaison Worker. The role included screening individuals accessing Accident and Emergency (A&E) using the Alcohol Use Disorders Identification Test (AUDIT; developed by The World Health Organisation in 1982; WHO, 2001) followed by the provision of a Brief Intervention (BI) for alcohol if deemed suitable. A number of individuals repeatedly presented following alcohol consumption, suffering from acute diabetes related complications such as hypo or hyper-glycaemia. I began providing 1:1 weekly support for two individuals, who both reported feeling diabetes self-management was complicated by alcohol consumption and insufficient support was provided regarding alcohol as part of routine diabetes care. A search of available literature and discussions with both Liver and Diabetes Specialist Consultants revealed a lack of awareness of the prevalence of alcohol use for this population or the impact of alcohol on adherence to self-care behaviours, but a general consensus that alcohol consumption negatively impacted ability to self-care.

I approached a Research Supervisor at the University with my thoughts on the interplay between alcohol use and diabetes self-management, and with my clinical experience of the negative correlation between the two. I was interested to discover that two University Research Supervisors, one with an interest in the alcohol field, and the other within medical psychology, were interested to co-supervise in the development of the idea as a research project. I therefore felt reassured of the provision of access to expertise and knowledge required to shape the research idea to fit with the requirements of a Doctorate in Clinical Psychology Thesis.

During the Doctorate I conducted a literature review examining the impact of

alcohol consumption on adherence to self-care behaviours and the management of diabetes

(Knott, 2010). This confirmed a negative correlation between alcohol and adherence to

self-care behaviour, with accessing medical care being cited as most frequently affected.

A second literature review, focusing on factors affecting self-care in Type 2 diabetes,

revealed a prevalence of low adherence in those with Type 2 diabetes (Osterberg &

Blaschke, 2005). As self-care of those with Type 2 diabetes differ greatly from those of

Type 1 (Siggurdottir, 2004), and Type 2 constitutes 90% of those diagnosed with diabetes

(WHO, 2011), a decision was made to focus the research project upon Type 2 diabetes.

During the development of research ideas and questions I was encouraged to meet

with a Professor of Diabetes Medicine and active researcher in diabetes. This proved

useful in shaping the research idea and in considering the feasibility of the study. Initially I

proposed to run a feasibility study, training staff working in diabetes care to provide BIs for

alcohol for individuals with Type 2 diabetes in routine appointments. I planned to assess

the efficacy of BIs in reducing alcohol consumption and examine the impact of any changes

in alcohol use on adherence to self-care. Following the Intervention I planned to run staff

focus groups to explore the feasibility of incorporating BIs into routine diabetes care. The

proposed study would improve upon a prior study by Ramsey *et al.* (2010), conducted in

the United States of America, which utilised a small population (14 in a BI group, and 14 in

a treatment as usual group) and utilised doctoral level Clinical Psychologists to perform the

intervention.

I was advised by the Professor of Diabetes Medicine that as prevalence of alcohol

use was unknown in this population and the impact of alcohol consumption on adherence to

self-care unclear, the project would be better grounded by examining patterns of alcohol use in this population, followed by a brief pilot study. This would provide a basis for future larger Randomised Controlled Trials (RCTs) to examine the efficacy and feasibility of inclusion of BIs into routine diabetes care. It was also felt that a large scale feasibility study would be resource and time-consuming, as large numbers of Diabetes Clinic staff would require training in the provision of BIs and would have to implement the intervention with a large enough sample size to provide adequate statistical power for analysis. Examining the prevalence of alcohol use followed by a pilot study would be more feasible to conduct within time and financial limitations, whilst providing useful data for this under-researched area.

Research Methodology

I was aware of the limits imposed by utilising a cross-sectional design, particularly as I was unable to infer strength and direction of causal relationships from analyses. As 0.4 whole time equivalent of my full-time post was allocated for this project, this imposed time limitations. I therefore arrived at the conclusion that a study of cross-sectional design was the most feasible design given constraints. Notably, many other projects being conducted by the Diabetes Research Network (DRN) were longitudinal or RCT's, however these were often in receipt of large funding grants and allocated larger teams of researchers, with longer time periods for completion.

I was aware when planning methods of recruitment that by recruiting individuals accessing General Practitioner (GP) surgeries, Diabetes Clinic appointments and registered

with a Diabetes Research Centre (DRC) research list, I would be accessing a pool of participants already demonstrating some level of adherence. This may have biased results, as I was not accessing those demonstrating poor adherence to attending regular diabetes check-up appointments. Given time and financial constraints placed upon the study, overcoming this issue was fraught with difficulty and ethical issues, as potential participants not attending diabetes appointments would need to be visited at home or sent out questionnaire packs following non-attendance of appointments; both methods may have resulted in the individuals feeling pressurised.

Ethical approval

Gaining ethical approval for the study was fraught with a number of difficulties and delays. Support was provided by the DRC, which formed part of the Diabetes Research Network (DRN). Advice was provided regarding gaining approved from a Research Ethics Committee (REC) swiftly, with minimal amendments. I was advised of the importance of providing clear information in the application and writing in a style understandable to the lay person.

Following submission of the proposal to the Integrated Research Application System (IRAS), I attended a REC meeting. The REC requested further clarifications and a number of alterations to the protocol, including allowing participants more time to decide on participation. This had financial implications as information would be required to be posted to potential participants before they attended Diabetes Clinic appointments, a cost which had not originally been accounted for. University funds would not allow for this

additional cost, however the DRN agreed to support this cost if the study was adopted to the National Institute for Health Research (NIHR) Portfolio. Additional areas of clarification included the process of anonomysing participants to all but their care team, and addressing the RECs concern that distress caused by discussing alcohol may result in participants failing to attend future diabetes check-up appointments. I provided clarification on the method by which individuals would be allocated participant numbers, and referred to my clinical experience of providing BIs and how infrequently individuals would express embarrassment or distress when asked about experienced feelings of distress or required further support.

I commenced an application for the study's adoption to the NIHR portfolio, which would ensure ongoing access to support from the DRN, financial support and the assistance of a Research Nurse in identifying potential participants and with administration tasks. The application process included gaining peer reviews from two independent expert clinicians in the field of diabetes.

Alongside the process of applying to REC, an application was prepared for local Research Management and Governance (RM&G) departments of two Acute Trusts to gain approval to conduct the research. This was a lengthy process, as signatures were required from a number of different individuals at managerial level, whom I had not previously met. The processing of these applications also varied between differing Trusts, and difficulties arose regarding ongoing debate about the need for a Research Passport and background and health checks for me as Principal Investigator. As I had applied to the NIHR and the DRN for support, the applications were managed through the DRN, with the communication to each RM&G site often being conducted through staff at the DRN, complicating

communication at times.

Early in the planning process two GP surgeries were identified as recruitment points, and GPs linked to these practices contacted and preliminarily agreed to support the study in recruiting. When, following gaining of REC and RM&G approval, I re-contacted the clinicians I discovered that they were only willing to support the study if an application for the support of the Primary Care Research Network (PCRN) was completed, which would provide service support costs to surgeries. I therefore met with the locality manager at the PCRN who agreed to support an application to the PCRN for service support costs. I was however advised that the two identified GP surgeries in the past had recorded poor return rates for questionnaire mail-outs. I therefore agreed for the PCRN to identify three Research Site Initiative (RSI) level 2 practices that were highly experienced and motivated to engage in research and who experienced high return rates. One identified practice however lay within a different Trust, therefore an application to another RM&G department was required. This resulted in a substantial amendment being submitted to the REC.

All communication with each GP surgery initially was conducted through the PCRN and this therefore resulted in frustration related to complexities around communicating information. To note, the applications to the PCRN, the new RM&G Trust and the substantial ethical amendment were submitted in late December 2012, therefore I was aware of the time delay in gaining approvals resulting from the Christmas break, which added to feelings of frustration as the study deadline was within sight.

Following the application for service support costs being approved by the PCRN, it was discovered that between the planning of the study and the application, the PCRN had

changed a policy on provision of finances to cover mail out of questionnaires. This had

significant implications for the study, resulting in a decision to cap the number of

questionnaire packs mailed out to 200 for each surgery. Further financial support for this

cost had to be negotiated with the University.

Conducting the research

Commencement of participant recruitment began with difficulty. Little time was

available to meet and form relationships with staff at the Diabetes Clinic, and staff were

rarely consistent in shift patterns. I believe this affected the willingness of staff to

distribute and collect questionnaire packs, as was originally proposed. It was planned that I

would initially attend the Diabetes Clinic to recruit and meet with staff, then staff would

recruit on my behalf by giving out questionnaire packs. However, staff were approached to

recruit, this was met with resistance and a number of potential participants were missed by

staff and returned questionnaire packs were not stored securely. This significantly

increased time pressures upon myself as I was required to attend every Diabetes Clinic.

The Diabetes Clinic reported high numbers of non-attendees, therefore at times,

particularly during poor weather conditions, small numbers of individuals attended or

clinics were cancelled, therefore smaller numbers of participants than was estimated were

recruited through this method. Of a total 225 potential participants, 119 were recruited, 52

failing to attend and 14 cancelling appointments; a further 24 refused to participate, 11

were unable to read or write and five were missed. Most individuals when approached to

participate were willing, stating that they were either interested in the research or saw the

questionnaires as 'something to do', as waiting times at the Diabetes Clinic could be lengthy.

Commencement of recruitment through GP surgeries was delayed. The PCRN asked for practice briefings to be drafted, which required submitting to REC for approval, and copies of all documents sent to each practice prior to their agreement to support the study. Geographically, delivering questionnaire packs to surgeries at short notice was challenging. However, surgeries were extremely supportive of the study and sent questionnaire packs to participants within days of having received them. I was thankful for the PCRN for the provision of service support costs for each surgery, therefore allowing practice staff to devote protected time to screening for participants and mailing out questionnaire packs. Due to the PRCNs inability to cover mail out of questionnaire packs, a reduced number of participants were mailed with each surgery limited to 200. Of the 600 packs sent out 117 were returned.

The supporting Research Nurse at the DRC also suggested utilising the list of individuals registered to partake in research held by the DRC as another point of recruitment. At this point sufficient numbers were not being recruited from the Diabetes Clinic, therefore gaining another point of recruitment was important. An amendment to REC was submitted, and recruitment was commenced swiftly, with a high rate of response from participants. Of 94 mailed out 43 responded, most expressing a willingness to partake in Stage 2 of the study.

A key change was made to the protocol for Stage 2 of the study due to feasibility issues. Initially one research question was regarding whether BIs were feasible to include

in routine diabetes care. Following discussion with staff at the DRC around the feasibility of training clinicians in BI, practicality issues arose. It was expressed that within a limited time scale, considering the high workload of staff working in diabetes care, it would not be feasible to train sufficient numbers of staff in the provision of BIs or for staff to carry out additional work to their usual duties. I therefore planned to perform the BI, and as a result could only speculate as to whether BIs were feasible to include in routine diabetes care. Further focus groups with staff or pilot studies trialling staff providing the intervention should be conducted to examine this.

Limitations of the research

One limitation of the study was the change to the protocol that saw myself performing the BI for alcohol, rather than staff working within diabetes care settings. This reduced my ability to answer the question 'is a BI for alcohol feasible to include in routine care?' and also failed to follow the recommendations for use of BI as being an opportunistic intervention, as participants arranged pre-arranged appointments some time after completion of the AUDIT. Additionally, the specialist knowledge of clinicians working routinely within diabetes care would allow for adaptation of BIs for use specifically with this population. My expertise mainly lay within the field of alcohol misuse, however a number of participants in Stage 2 expressed complex queries regarding the interaction between alcohol and diabetes related complications or medications and difficulties specific to this population, regarding for example finding low-sugar non-alcohol beverages in public houses, which had not previously been considered. Further research should examine

how BIs for alcohol should be adapted specifically for individuals with Type 2 diabetes.

Another limitation of the study related to sample sizes. Due to recruitment difficulties in Stage 1 of the study, sufficient numbers of participants were not recruited to provide adequate statistical power to meet a preferred confidence interval of 95% for analysis, therefore a 10% error rate was utilised. Sufficient numbers were not recruited to meet estimated sample size for Stage 2, however, as this was a pilot study, and further RCTs would be recommended, the number recruited were sufficient to draw preliminary ideas regarding the efficacy and feasibility of providing BIs for alcohol for this population. The generalisability of findings of Stage 1 should also be considered, as I was unable to recruit those who didn't access clinics or GP surgeries and was unable to include non-English speakers due to lack of resources to do so, this therefore may have resulted in biasing of results. As the result of the mail-out of some questionnaires, I was unable to record reasons for non-participation, which would have proved useful.

The measures utilised had limitations, particularly the reliance on self report. Self-report does have suggested reliability when examining for example medication adherence (Bodenheimer *et al.,* 2002), however reliability of findings may have been further improved by accessing medical files for biological measures, such as most recent blood sugar measure, or records of attendance of appointments. It was felt that ethical requirements surrounding gaining access to medical files would have been complex and would have required lengthy negotiation with each team regarding supervision of access to files. An alternative would have been to recruit a member of the DRN to conduct this work, however finances allocated to the project would not have covered the cost of doing so.

The Self-Care Inventory Revised (SCIR; La Greca, 1992) was utilised as a measure of adherence, as my literature review revealed that a good measure of adherence should be easy to use and of low cost, validated, and give clear evidence of the degree of adherence to specific activities in diabetes self-management (Hearnshaw & Lindenmeyer, 2005). The SCIR was developed in conjunction with focus groups of diabetes educators and found to have sufficient validity for use in this population (Weinger *et al.,* 2005; Khangram *et al.,* 2013). The SCIR however caused some participants confusion as a number of the self-care behaviours were applicable to Type 1 diabetes.

The AUDIT, developed by the WHO in 1982 (WHO, 1991), was used as a measure of patterns of alcohol use, as National Institute for Health & Clinical Excellence guidelines (NICE, 2011) refer to the measure as one of the most reliable estimates of alcohol dependence. It was also already in use within this geographical area, therefore I hoped that it would be a familiar tool to clinicians. Due to the nature of both tools, a limited number choices were available in response to each question and some participants expressed frustration at the forced choice. Both measures were relatively quick to administer in a busy clinic waiting room environment however (estimated to take 7 minutes to complete).

I was not able to include a measure of all variables indicated to affect adherence to self-care behaviours in the literature in the Demographic Pro-forma, as the measure was required to be short and feasible to complete within minutes. The Pro-forma included measures of age and gender, both suggested to affect adherence (Gomersall *et al.,* 2011; Peeters *et al.,* 2010), but failed to measure social support (Schiotz *et al.,* 2011), depression (Egede *et al.*, 2009) or self-efficacy (Nelson *et al.*, 2007), due to complexity of measuring these concepts. Additionally, future research should measure years since diagnosis and

stage of change (Prochaska & Diclemente's Stage of Change Model, 1983; Prochaska *et al.,* 1992). A number participants in Stage 2 had received their diagnosis within the past 5 years and expressed difficulties with accepting the diagnosis and a lack of information regarding the chronic disorder and its management. They may have been considered at the Pre-contemplative stage of change according to Prochaska and Diclemente's Model, which may have impacted the efficacy of the BIs less likely.

Personal reflections on the process as a whole and what has been learnt

A primary learnt point was that allowances for setbacks should be built into time-tables, and contingency plans should be put in place when conducting a research project. A number of setbacks were encountered, but due to abilities to work under pressure and forethought of having put in place a number of contingency plans, the project was able to recover. Strategies to self-manage anxiety and frustrations associated with setbacks were also utilised throughout.

At times managing competing demands of clinical work, University research demands, the NIHR and DRN research demands and personal commitments was difficult. Throughout the process high levels of anxiety were experienced related to depending on others, feeling a lack of control over the project, and hoping that others' goodwill would ensure that the project would be carried forward. The support and involvement of a number of research networks also increased the complexity in regards to communication of any changes or queries, but also provided support at times. The number of changes submitted to REC were also frustrating and time consuming: one substantial and two minor, due to the evolving

nature and learning process involved in the project. The research process required the learning of a 'new language' and complex set of processes to navigate RECs, RM&Gs and to communicate with research networks.

Implementing and managing the project highlighted the importance of developing relationships with those involved in the research and being aware of conflicting agendas and others' workload pressures. Numerous meetings with research networks, GP surgeries and clinics were attended to develop relationships; these were both time consuming and at times anxiety provoking, due to the scrutiny that my project received and the possibility that my inexperience, in comparison with experienced researchers, could be highlighted.

I learnt to balance gently encouraging others to do what was required of them for the study, without appearing overly assertive, which may have resulted in withdrawal of support. Professionalism and courtesy were retained at all times, demonstrating awareness and empathy for others' workloads, whilst highlighting the pressures of the project. Clinical Psychology training and clinical experience aided the forming of relationships with professionals. The training was also useful when approaching participants: some questions within measures yielded difficult answers, for example asking for relationship status when a participant was recently widowed. I learn how to gain required information sensitively whilst maintaining boundaries and awareness that I wasn't in a clinical role there to support participants, but in the role of Researcher.

Throughout the Study envy was experienced towards the research teams that I worked alongside. I was acutely aware of my own stressors and frustrations, and felt that working as a team would share and minimise the pressures. I struggled with ill-health at

points during the Study, but felt that I could not allow myself time off. As the sole person conducting the research, I was required to learn about every different part of the process and it felt that I needed to always be contactable and be everywhere. This did however heightened my interest in conducting research as part of a team, rather than as an individual. Being organised was paramount and re-checking all documentation key; major set-back was suffered when an error in a number of questionnaire packs resulted in a number of questions missing from the AUDIT, and as an overall score was required, this excluded a number of participants' results from inclusion in the analysis. This highlighted the importance of checking all details within documents.

Throughout the process I learnt to be comfortable sitting with uncertainty. I found relying on others was a weakness of mine, as I felt high levels of anxiety when others held responsibilities within the project. I very much lacked any feelings of control over the process at times, particularly when waiting for the PCRN to recruit GP surgeries and when waiting for questionnaire packs to be sent out.

During the course of the research, questions and comments arose from participants regarding alcohol and diabetes, and their experiences regarding the support and advice they had received about alcohol as part of their routine diabetes care. I felt that it would have been useful to include a qualitative aspect to my study, to gain information regarding what service users and clinicians felt about the subject, and how they felt BIs for alcohol should be adapted according to specific difficulties associated with diabetes. This also highlighted my lack of knowledge regarding the complexity of conducting BIs in a diabetic population.

Finally, the lessons learnt have helped clinically. My third year clinical placement

was within a medical setting, working with chronic health conditions. The experiences gleaned from the research project helped my understanding of the complexities of self-management of chronic conditions and the importance of collaborative care and integrative working.

Future Research Strands and Opportunities

Future research should include qualitative studies examining service user experience of support in relation to alcohol consumption, and their anxieties and concerns around alcohol use and diabetes. Focus groups of staff members would be useful to gain staff opinion on the inclusion of BI in routine diabetes care and its adaptation specifically for this population.

Future research should examine the feasibility of training and asking clinicians working within diabetes care to provide BIs opportunistically, as intended. An RCT with a larger cohort would allow for the efficacy of BIs in this population, and its impact on adherence to self-care further examined. Inclusion of biological measures or screening of medical files for information relevant to adherence would strengthen findings, rather than reliance solely on self-report.

Future research should address the need to access those with complex needs, for example individuals failing to attend regular Diabetes Clinic or GP appointments. These individuals could be accessed through routine screening and signposting of those with diabetes accessing A&E services as the result of poorly controlled diabetes or those

accessing alcohol support services. Future studies should also include non-English speakers, due to the high incidence of diabetes in certain ethnicities, up to six times more likely in individuals of South Asian descent; up to three times more likely in those of African and African-Caribbean descent (diabetes UK, 2013).

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Appendices

Appendix A Literature review database search

Database	Rationale	Search terms	Number of articles
EBSCO-psychinfo and psycharticles	To gain access to journals with a psychological view on what may be considered a medical area. Limited search to January 2003 onwards, peer reviewed, academic journals and excluded non-articles and studies looking at under 18's.	'diabetes' (title) + 'self care' (title)	82
		'diabetes' (title) + 'barriers'(title)	28
		'diabetes' (title) + 'adherence' (title)	93
		'diabetes' (title) + 'self-management' (title)	176
		'diabetes' (title) + 'facilitators' (title)	1
		'diabetes' (title) + 'levers' (title)	0
		'diabetes' (title) + 'enablers' (title)	0
Wiley online library-ejournals	To gain access to a wide range of journals. Limited search to2003-2013, adult population.	diabetes (article title) + 'self-care' (diabetes title)	41
		'diabetes' (article title) + self-management' (diabetes title)	0
		'diabetes' (article title) +	

		'adherence' (article title)	53
		'diabetes' (article title) + 'barriers' (article title)	41
		'diabetes' (article title) + 'facilitators' (article title)	6
		'diabetes' (article title) + 'levers' (article title)	1
		'diabetes' (article title) + 'enablers' (article title)	0
PubMed	To gain access to a medical perspective. Limited to articles published in the last 10 years, with an adult population, published in English.	'diabetes' (title) + 'self-care' (title)	112
		'diabetes' (title) + 'self-management' (title)	284
		'diabetes' (title) + 'adherence' (title)	187
		'diabetes' (title) + 'barriers' (title)	60
		'diabetes' (title) + 'facilitators' (title)	8
		'diabetes' (title) + 'levers' (title)	0
		'diabetes' (title) + 'enablers' (title)	0

Medline (Ovid Sp) Journals@ovid full text, Your Journals@ovid	To gain access to medical resources. Limited to published between 2003-2013, excluded psycharticles.	'diabetes' + 'self care' (title)	8
		'diabetes' + 'barriers'(title)	0
		'diabetes' + 'adherence' (title)	0
		'diabetes' + 'self-management' (title)	0
		'diabetes' + 'facilitators' (title)	0
		'diabetes' + 'levers' (title)	0
		'diabetes' + 'enablers' (title)	0
Web of Science	To gain access to scientific journals. Limited to English language journal articles and reviews, published 2003-2013.	'diabetes' + 'self care' (title)	151
		'diabetes' + 'barriers'(title)	136
		'diabetes' + 'adherence' (title)	270
		'diabetes' + 'self-management' (title)	377
		'diabetes' + 'facilitators' (title)	20
		'diabetes' + 'levers' (title)	1
		'diabetes' + 'enablers' (title)	1
Cochrane	To gain access to systematic reviews of the relevant literature.	'diabetes' (title, abstract, keyword)	182
		'diabetes self-care' (title,	

	Limited to reviews.	abstract, keyword)	5
		'diabetes barriers' (title, abstract, keyword)	1
		'diabetes adherence' (title, abstract, keyword)	6
		'diabetes self-management' (title, abstract, keyword)	5
		'diabetes' + 'facilitators' (title)	2
		'diabetes' + 'levers' (title)	0
		'diabetes' + 'enablers' (title)	0
Searched 'related citations' when available in search engines, when relevant articles were found	To enable access to related articles that search terms may not have uncovered.	N/A	2
Manually searched references of	To allow access to related articles or similar studies that may not have been	N/A	3

key articles	available on the search engines used, or search terms may not have uncovered them.		
Contacted key names in the research area.	To allow access to published or unpublished research not available on databases searched.	N/A	0
		Total number:	2343
		Total number following removal of duplicates:	1090
		Articles deemed relevant after reading abstracts:	106
		Articles deemed relevant following application of inclusion criteria:	19

Appendix B Literature review inclusion/exclusion criteria

Inclusion criteria: studies examining psychosocial factors influencing adherence to self-care behaviours in those diagnosed with Type 2 diabetes; published from 2003 onwards, in peer reviewed, English language journals; utilising an adult population (18 years +, with no upper age limit); carried out in Western populations; studies were only included if they scored 18/32 or over on the STROBE quality of reporting tool.

Exclusion criteria: studies which included participants diagnosed with Type 1 diabetes, both Type 1 and Type 2 diabetes and not showing separate analysis of data, including individuals not diagnosed with diabetes or samples including other long-term conditions; published prior to 2003 as this would provide the most up to date literature from the past ten years and also ensure that the yield of literature was not overwhelming; not published in peer reviewed journals; reviews, professional opinions, letters, short reports and non-studies; studies looking fixed factors such as gender and ethnicity as these factors had previously been examined in reviews and research suggests that psychosocial factors have greater impact on adherence; studies addressing the impact of non-individual factors e.g. care or physician factors as these had previously been reviewed; carried out in non-Western populations due to differing healthcare provision and cultural variation making comparison of studies difficult; studies were excluded if they scored less than 18/32 on the STROBE quality of reporting tool as it was deemed that their due to limited reporting studies could not be fully assessed for methodological quality.

Appendix C Flowchart diagram of the literature search process, following PRISMA guidelines

```
┌─────────────────────────────┐          ┌──────────────────────────────────┐
│ 2340 articles identified     │          │ 3 articles identified through     │
│ through database search      │          │ other sources:                    │
│                              │          │ 2 identified by manually searching│
└─────────────────────────────┘          │ references of key articles, and 1 │
                                          │ identified by searching the list  │
                                          │ of 'relevant citations' in search │
                                          │ databases                         │
                                          └──────────────────────────────────┘
                    │                                  │
                    ▼                                  ▼
        ┌───────────────────────────────────────┐
        │ 1090 articles after duplicates were   │
        │ removed                               │
        └───────────────────────────────────────┘
                    │
                    ▼
        ┌───────────────────────────────────────┐      ┌──────────────┐
        │ 1090 articles screened, by searching  │ ───▶ │ 984 articles │
        │ titles for relevance                  │      │ excluded     │
        └───────────────────────────────────────┘      └──────────────┘
                    │
                    ▼
        ┌──────────────────────┐      ┌────────────────────────────────────┐
        │ 106 full text        │      │ 87 full-text articles excluded: 21  │
        │ articles screened    │      │ of qualitative/mixed methodology; 9 │
        │ for eligibility,     │ ───▶ │ focused on fixed factors such as    │
        │ with the application │      │ gender; 2 focused on organisational/│
        │ of the exclusion     │      │ physician factors; 6 recruited Type │
        │ criteria             │      │ 1 and 2, but not distinguishable, 1 │
        └──────────────────────┘      │ included non-diabetic participants, │
                    │                 │ and 1 participants with Type 1      │
                    │                 │ diabetes; 6 used an adolescent      │
                    │                 │ population; 14 drew exclusively from │
                    │                 │ a Chinese population; 2 examined the │
                    │                 │ impact of an intervention on diabetes│
                    │                 │ self-care; 1 explored diabetes       │
                    │                 │ prevention; 1 focused on adherence to│
                    │                 │ Mediterranean diet; 5 consisted of   │
                    │                 │ brief reports with little detail; 4  │
                    │                 │ were found to be reviews; 2 examined │
                    │                 │ the impact of adherence or diabetes  │
                    │                 │ symptoms on psychosocial variables; 4│
                    │                 │ claimed to examine psychosocial      │
                    │                 │ variables, but not confirmed under   │
                    │                 │ scrutiny; 8 due to STROBE application │
                    ▼                 └────────────────────────────────────┘
        ┌───────────────────────────────┐
        │ 19 articles were included in   │
        │ the quantitative synthesis     │
        └───────────────────────────────┘
```

Appendix D Literature review quality appraisal tool

The STROBE was the chosen quality appraisal tool for this review as it is endorsed

by over 100 journals (da Costa, Cevallos, Altman, Rutjes & Egger, 2010) and has been

utilised in a recent relevant systematic review (Ricci-Cabello, Ruiz-Pe´rez, Olry de Labry-

Lima Ma´rquez-Caldero´n, 2010). The use of the STROBE checklist is limited as it is ever

evolving as new critiques and evidence arises, therefore the quality appraisal used in the

current review may vary from others using the same tool in past or future reviews.

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why

Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) If applicable, describe analytical methods taking account of sampling strategy
		(*e̱*) Describe any sensitivity analyses

Results

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
Outcome data	15*	Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses

Discussion

Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results

Other information

Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

Appendix E Table demonstrating quality of reporting of each article in line with the STROBE checklist

Study														STROBE item																			T
	1a	b	2	3	4	5	6	7	8	9	10	11	12a	b	C	d	E	13a	b	C	14a	b	15	16a	b	c	17	18	19	20	21	22	
Bailey	0	1	.5	1	1	.5	1	1	1	0	0	0	.5	0	0	0	0	.5	0	0	.5	0	1	0	0	0	1	1	.5	1	1	0	14
Baquedano	1	1	.5	1	1	1	1	.5	1	0	0	0	1	0	0	0	0	1	0	0	.5	0	1	.5	0	0	0	1	0	.5	.5	0	14
Bezie	0	1	.5	.5	.5	.5	.5	.5	.5	0	0	1	.5	0	0	0	0	.5	0	0	1	0	1	0	1	0	0	1	.5	1	0	0	12
Chlebowy	0	1	1	1	1	.5	1	1	1	0	0	0	0	0	0	0	0	0	0	0	1	0	1	.5	0	0	1	1	0	1	0	0	13
Daly	1	1	.5	1	1	.5	1	1	1	0	0	1	.5	1	0	0	0	1	0	0	.5	0	1	.5	1	0	1	1	1	1	1	.5	20
Egede	0	1	1	1	1	1	1	1	1	0	0	1	1	1	0	0	0	0	0	0	1	0	1	1	1	0	1	1	1	1	0	0	19
Gonzalez	0	1	1	1	1	1	.5	1	1	0	0	0	1	1	0	0	1	1	0	0	1	0	1	1	1	0	1	1	1	1	1	1	21.5
Lerman	1	1	0	1	1	1	1	.5	1	0	0	1	.5	0	0	0	0	0	0	0	1	0	1	.5	0	0	1	1	.5	1	0	0	15
Mann	0	1	1	1	1	1	1	1	1	0	0	1	1	0	0	0	0	0	0	0	1	0	1	0	1	0	1	1	1	1	1	1	19
McKellar	0	1	1	.5	1	.5	1	.5	1	0	0	1	1	1	0	0	0	0	0	0	1	0	1	1	0	0	0	1	1	1	1	1	17.5
Montague	0	1	1	.5	1	0	1	0	1	0	0	0	1	0	0	0	0	0	0	0	1	0	1	0	1	0	1	1	1	1	1	0	14.5
Nelson	0	1	1	.5	1	1	1	1	1	0	0	1	1	1	0	0	0	1	1	0	1	0	1	1	1	0	1	1	1	1	1	1	22.5
Nouwen	1	1	1	.5	1	1	1	1	1	0	0	1	1	1	0	0	0	.5	0	0	1	0	1	1	0	0	1	1	1	1	.5	0	19.5
Osborn (2010)	0	1	1	1	1	1	1	1	1	0	.5	1	1	1	0	1	.5	0	0	0	1	0	.5	1	0	0	.5	1	.5	1	1	0	19.5
Osborn (2012)	0	1	1	1	1	1	1	1	1	1	0	1	1	1	0	0	0	0	0	0	1	0	1	1	1	0	1	1	1	1	1	0	21
Samuel-Hodge	1	1	1	.5	1	0	1	.5	1	0	0	1	1	1	0	0	0	0	0	0	1	0	1	1	0	0	1	1	1	1	1	0	18
Schiotz	0	1	.5	.5	1	1	.5	.5	1	0	0	1	1	1	1	0	1	1	0	1	1	0	1	1	1	0	1	1	1	1	1	0	22
Shigaki	0	1	1	1	1	0	1	1	1	0	0	1	1	1	0	1	1	1	1	0	1	0	1	1	1	0	1	1	1	1	1	0	23
Smalls	0	1	1	1	1	1	1	1	1	0	0	1	1	1	0	0	0	0	0	0	1	0	1	1	1	0	1	1	1	1	1	.5	20.5
Tang	1	1	1	1	1	.5	1	1	1	0	0	1	1	1	0	0	0	0	0	0	1	0	1	1	0	0	1	1	1	1	1	.5	20
Tiv	0	1	.5	.5	1	1	1	1	1	0	0	1	1	1	0	1	.5	1	0	0	1	0	1	1	1	0	.5	1	1	1	1	1	22
Villas-Boas	1	1	.5	.5	1	1	.5	.5	1	0	0	1	1	1	0	0	0	1	1	0	1	0	1	.5	0	0	1	1	1	1	0	0	18.5
Walker	0	1	1	1	1	1	1	1	1	.5	0	1	1	1	0	0	0	0	0	0	1	0	1	1	1	0	1	1	1	1	1	.5	21
Wanko	0	1	.5	1	1	1	1	.5	.5	0	0	1	1	1	0	0	0	0	0	0	1	0	1	1	0	0	.5	1	1	1	0	0	16
Weijman	0	.5	.5	1	1	.5	1	.5	1	0	0	1	1	1	0	0	0	1	0	0	1	0	1	1	.5	0	1	1	1	1	1	.5	19
Whittemore	1	1	1	1	1	.5	1	1	1	0	0	1	1	1	0	0	0	1	1	0	1	0	1	1	0	0	1	1	1	1	1	.5	22
Yamashita	0	1	1	1	0	1	1	1	1	0	0	1	1	1	0	1	0	0	0	0	.5	0	1	0	0	0	1	1	1	1	1	.5	18

Appendix F Alcohol Use Disorders Identification Test (AUDIT)

This is one unit of alcohol…	Half pint of regular beer, lager or cider	1 small glass of wine	1 single measure of spirits	1 small glass of sherry	1 single measure of aperitifs

…and each of these is more than one unit	2	3	1.5	2	4	2	9
	Pint of Regular Beer/Lager/Cider	Pint of Premium Beer/Lager/Cider	Alcopop or can/bottle of Regular Lager	Can of Premium Lager or Strong Beer (440ml)	Can of Super Strength Lager (440ml)	Glass of Wine (175ml)	Bottle of Wine

AUDIT

	Scoring system					Your score
	0	1	2	3	4	
How often do you have a drink containing alcohol?	Never	Monthly or less	2 - 4 times per month	2 - 3 times per week	4+ times per week	
How many units of alcohol do you drink on a typical day when you are drinking?	1 -2	3 - 4	5 - 6	7 - 9	10+	
How often have you had 6 or more units if female, or 8 or more if male, on a single occasion in the last year?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
How often during the last year have you found that you were not able to stop drinking once you had started?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
How often during the last year have you failed to do what was normally expected from you because of your drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
How often during the last year have you needed an alcoholic drink in the morning to get yourself going after a heavy drinking session?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
How often during the last year have you had a feeling of guilt or remorse after drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
How often during the last year have you been unable to remember what happened the night before because you had been drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily	
Have you or somebody else been injured as a result of your drinking?	No		Yes, but not in the last year		Yes, during the last year	
Has a relative or friend, doctor or other health worker been concerned about your drinking or suggested that you cut down?	No		Yes, but not in the last year		Yes, during the last year	

SCORE
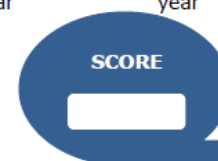
Appendix G Self-Care Inventory- Revised (SCI-R)

Self Care Inventory-Revised Version (SCI-R)

This survey measures what you *actually do*, not what you are advised to do. How have you followed your diabetes treatment plan in the past 1-2 months?

	Never ▼	Rarely ▼	Sometimes ▼	Usually ▼	Always ▼	
1. Check blood glucose with monitor	1	2	3	4	5	
2. Record blood glucose results	1	2	3	4	5	
3. If type 1: Check ketones when glucose level is high	1	2	3	4	5	Have type 2 diabetes
4. Take the correct dose of diabetes pills or insulin	1	2	3	4	5	Not taking diabetes pills or insulin
5. Take diabetes pills or insulin at the right time	1	2	3	4	5	Not taking diabetes pills or insulin
6. Eat the correct food portions	1	2	3	4	5	
7. Eat meals/snacks on time	1	2	3	4	5	
8. Keep food records	1	2	3	4	5	
9. Read food labels	1	2	3	4	5	
10. Treat low blood glucose with just the recommended amount of carbohydrate	1	2	3	4	5	Never had low blood glucose
11. Carry quick acting sugar to treat low blood glucose	1	2	3	4	5	
12. Come in for clinic appointments	1	2	3	4	5	
13. Wear a Medic Alert ID	1	2	3	4	5	
14. Exercise	1	2	3	4	5	
15. If on insulin: Adjust insulin dosage based on glucose values, food, and exercise	1	2	3	4	5	Not on insulin

Appendix H Demographics Pro-forma

University of Leicester

Demographic Data

Please tick the most relevant box.

Gender

Male ☐

Female ☐

Other ☐ (please specify)...

Age Group

25 or under ☐

26 to 40 ☐

41 to 55 ☐

56 or older ☐

Ethnicity

Asian or Asian British: Indian ☐

Pakistani ☐

Bangladeshi ☐

Any other Indian background ☐ (please specify)..................................

Black or Black British: Caribbean ☐

African ☐

Any other Black background(please specify)..................................

White: British ☐

Any other White background ☐ (please specify)...................................

Chinese ☐

Mixed ethnicity ☐ (please specify)...................................

Other ☐ (please specify)...

Marital Status

Single ☐

Co-habiting ☐

Married ☐

Divorced ☐

Separated ☐

Widowed ☐

Other ☐ (please specify)...

Employment

Full-time employment ☐

Part-time employment ☐

Retired ☐

Unemployed ☐

Self-employed ☐

Student ☐

Unable to work ☐

Other ☐ (please specify)...

Appendix I Letters of approval from NREC local R&D, NIHR portfolio

NHS
Health Research Authority

29 June 2012

Dear Mrs Knott,

Study Title:	**A prevalence study of alcohol consumption and adherence to self-care behaviours of those with Type 2 diabetes; followed by a pilot study to develop and refine Brief Interventions for alcohol and consider what impact this would have on adherence to diabetes self-care behaviours and explore whether this would be feasible to include in routine diabetes care**
REC reference:	**12/EM/0238**
Protocol number:	**N/A**

The Research Ethics Committee reviewed the above application at the meeting held on 21 June 2012. Thank you for attending to discuss the study.

Documents reviewed

The documents reviewed at the meeting were:

Document	Version	Date
Interview Schedules/Topic Guides: Focus Group	1	20 January 2012
Investigator CV		20 January 2012
Letter of invitation to participant	1	20 January 2012
Other: GCP Certificate - Katy Knott		17 April 2012
Other: CV -		14 February 2012
Other: CV -		01 November 2011
Other: Cover letter for questionnaires/consent	1	20 January 2012
Other: Letter to Responsible Clinician of participant results/concerns	1	20 January 2012
Other: Debriefing Sheet	1	20 January 2012
Other: Brief Intervention Questions: Guidance Questions for Staff	1	20 January 2012
Other: Summary newsletter for participating clinics/surgeries		
Other: Research Flowchart	1	20 January 2012

A Research Ethics Committee established by the Health Research Authority

Other: Useful information and contact numbers	1	20 January 2012
Other: Brief Interventions Leaflet		
Participant Consent Form	1	20 January 2012
Participant Information Sheet	1	20 January 2010
Protocol	1	20 January 2012
Questionnaire: Demographic Data	1	20 January 2012
Questionnaire: SC1-R		
Questionnaire: Audit		
REC application	96612/329521/1/477	27 May 2012

Provisional opinion

- The committee asked you whether it is anticipated to cause problems that participants care team or GP will be informed of their involvement in the study. You stated that it will be made clear to participants and that they decide whether they want to consent to this, but they would try and minimize any potential embarrassment.

- The committee raised the point that participants may not want to attend clinic as they may not want to confront the amount of alcohol they drink. You confirmed that the participant's care team does not have to be involved, and that they wouldn't push participants in anyway.

- The committee asked you how the Participant Information Sheet and Consent Form will be given to participants, and whether the invitation letter will be given by their care team. You confirmed that the invitation letter will be sent to participants only in the second stage of the study which would be accompanied by the Participant Information Sheet.

- The committee asked you whether returning the questionnaire is implied consent. You confirmed that it is.

- The committee asked you if part 1 of the study is anonymous and if so how can they be selected for the focus group. You confirmed that she herself would be blinded and other members of the research team would code each questionnaire. The committee went on to ask whether it will be apparent which participant came from which clinic. You confirmed that this could be identified.

- The committee stated to you that the application form states that the study has been statistically reviewed but nothing was submitted. You confirmed that this is an on going matter, and that she brought with her email correspondence for the committee to see.

- The committee asked you why a debrief letter will be given to participants as the committee do no think that this is necessary. You explained that this for the participants benefit if they wanted certain contact details and just a reminder of these. The committee suggested that this should just be included in the Participant Information Sheet rather than a separate document. You agreed.

- The committee stated that focus groups will be done to test the feasibility of the study, however there is no reference to how these staff will be recruited. You confirmed that they will be recruited from GP surgeries and various other sites.

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- The committee asked you whether the staff for the focus group will be consented. You confirmed that they will be consented and didn't submit the Participant Information Sheet and Consent Form as she wasn't sure if it was relevant. The committee stated that these documents will need to be submitted.

- The committee asked you to confirm whether participant's personal data will be kept on a USB device. You confirmed that it would be on her own USB device. The committee went on to say that this is not usually accepted and a different method should be chosen, the committee suggested that you should look at the data protection act.

- The committee suggested that the Participant Information Sheet wording should be more sensitive.

- The committee asked you whether she will have enough time to analyses the proposed 344 questionnaires in 6 months. You stated that the diabetes clinics would recruit participants, so she will have enough time.

The Committee is unable to give an ethical opinion on the basis of the information and documentation received so far. Before confirming its opinion, the Committee requests that you provide the further information set out below.

The Committee delegated authority to confirm its final opinion on the application to the Chair.

Further information or clarification required

1. The Participant Information Sheet and Consent Form for staff in the focus group should be submitted.

2. Confirmation was sought as to what method will be used to store participant's personal data.

3. The invitation letter should be submitted.

4. The debrief sheet should be included in the Participant Information Sheet and not given as a separate document.

5. The following amendments are required to the Participant Information Sheet:
a) The amount of time to consider the study should be specified
b) Part 1 and Part 2 should be separate Participant Information Sheets
c) Part 2 should include the standard NRES headings (there is guidance for this on the NRES website)
d) It should be explicit as to how long data will be kept for
e) It should be explained that the study is part of an educational programme and is toward a doctorate

6. The different variations of the letter to the responsible clinician should be submitted.

If you would find it helpful to discuss any of the matters raised above or seek further clarification from the Committee Co-ordinator, you are welcome to contact

When submitting your response to the Committee, please send revised documentation where appropriate underlining or otherwise highlighting the changes you have made and giving revised version numbers and dates.

If the committee has asked for clarification or changes to any answers given in the application form, please do not submit a revised copy of the application form; these can be addressed in a covering letter to the REC.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 27 October 2012.

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

	Please quote this number on all correspondence

Yours sincerely

Chair

Email:

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments.*

Copy to:

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Hi

Thanks for getting back to me and helping by clarifying what I need to do. I've responded to each point below and attached all relevant documents. If there is anything more that you require however let me know.

In response to at the points raised for further information or clarification:

1. I have attached a Participant Information Sheet and Consent Form for staff focus groups.

2. I have sought advice and shall be storing personal identifiable information in paper form in a locked cabinet, in a locked room and identifiable information will not be removed from the participant identification sites. It will be stored seperately to any data collected to ensure that participants will not be able to be identified with their data. Personal identifiable information will only be retained for as long as the researcher is required to contact participants (maximum a month). All hard copies of questionnaires will be stored in a locked cabinet, in a locked drawer, and a secure university database will be used for storage of raw data scores, which will have access limited to the main researcher. This should be in line with the Data Protection Act and   policy.

3. I have attached an updated version of the participant invitation letter and invitation letter for staff to attend focus groups.

4. I have incorporated the debrief sheet into the Participant Information Sheet.

5.a)I have specified in the Participant Information Sheet that participants have up until 2 weeks to consider whether to participate in part 2 of the study, and participants in the staff focus groups have up until 2 weeks also.

b) 'Part 1 and Part 2 should be separate Participant Information Sheets': I have put together a brief Participant Information Sheet for part 1 of the study (attached participant information sheet part 1) to send out with appointment letters prior to potential participants attending routine appointments to give them information regarding the study prior to being given questionnaires. I hope that a short Participant Information Sheet is sufficient. I have not produced a lengthy Participant Information Sheet for stage 1 of the study as I felt a brief sheet would be sufficient as part 1 involves filling out questionnaires and not receiving interventions. This appears to be in line with the NRES guidelines I previously mentioned that state 'it is entirely acceptable to produce a single section information sheet for a short study and for a simple questionnaire study, sufficient information may be provided on the front of the questionnaire.'

c)I have included the standard NRES headings in the Participant Information Sheet for part 2 and staff focus groups as advised.

d) I have stated explicitly as advised that personal identifiable data will only be kept until the second questionnaires are sent out, however anonymous data will be stored for 5 years after completion of the research at   . I have also stated that all data will be disposed of securely in line with University policy after this time period has elapsed.

e) I have stated explicitly as advised that the study is part of an educational programme and is towards a doctorate.

6. Thanks for clarifying this point. Yes, in my view only one version of the letter will be sent to the RC if the participant has agreed to this occurring. The letter will be a standard letter that will inform the RC of the participation of their patient and will state the questionnaire results and whether these were a concern or not and whether further support is required. I have attached a copy of this updated letter

I have also ensured all version numbers and dates are in line on all forms.

Many thanks,

Katy

24 July 2012

Dear Mrs Knott

Study title:	**A prevalence study of alcohol consumption and adherence to self-care behaviours of those with Type 2 diabetes; followed by a pilot study to develop and refine Brief Interventions for alcohol and consider what impact this would have on adherence to diabetes self-care behaviours and explore whether this would be feasible to include in routine diabetes care**
REC reference:	**12/EM/0238**
Protocol number:	**N/A**

Thank you for your letter of 10 July 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

<u>Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.</u>

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Interview Schedules/Topic Guides	Focus Group 1	20 January 2012
Investigator CV		20 January 2012
Letter of invitation to participant	1	20 January 2012
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Other: Brief Interventions Leaflet		
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Participant Information Sheet	1	20 January 2010
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Participant Information Sheet: Staff Focus Groups	2	05 July 2012
Protocol	1	20 January 2012

Questionnaire: Demographic Data	1	20 January 2012
Questionnaire: SC1-R		
Questionnaire: Audit		
REC application	96612/32952 1/1/477	27 May 2012
Response to Request for Further Information		10 July 2012

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

<u>Reporting requirements</u>

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

<u>Feedback</u>

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

12/EM/0238	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Chair

Email:

Enclosures: "After ethical review – guidance for researchers"

24 July 2012

Dear Mrs Knott

Study title:	**A prevalence study of alcohol consumption and adherence to self-care behaviours of those with Type 2 diabetes; followed by a pilot study to develop and refine Brief Interventions for alcohol and consider what impact this would have on adherence to diabetes self-care behaviours and explore whether this would be feasible to include in routine diabetes care**
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Other: Useful information and contact numbers	1	20 January 2012
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Other: Participant Invitation Letter	2	05 July 2012
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Participant Information Sheet	2	05 July 2012
Participant Information Sheet: Staff Focus Groups	2	05 July 2012
Protocol	1	20 January 2012

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Questionnaire: SC1-R		
Questionnaire: Audit		
REC application	96612/32952 1/1/477	27 May 2012
Response to Request for Further Information		10 July 2012

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<u>Feedback</u>

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Further information is available at National Research Ethics Service website > After Review

12/EM/0238	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Chair

Email:

Enclosures: "After ethical review – guidance for researchers"

16/08/12

CSP Ref: 96612
REC Ref: 12/EM/0238
End Date: 28/02/13

Dear Katy Knott

I am pleased to confirm that   has reviewed your research study titled a prevalence study of alcohol consumption and adherence to selfcare behaviours of those with Type 2 diabetes; followed by a pilot study to develop and refine Brief Interventions for alcohol and consider what impact this would have on adherence to diabetes care using the Coordinated System for gaining NHS Permission (CSP) and gives approval for you to conduct this research within the Trust on the condition that the Trust suffers no costs as a result of this study being undertaken. Your research has been entered onto the Trust's Research Database.

The study documents receiving permission for use in the Trust are as follows:

Document Title	Version	Date	REC Approval
REC favourable opinion letter	N/A	24/07/12	N/A
Interview Schedules/Topic Guides-Focus Group	1	20/01/12	YES
Letter of invitation to participant	1	20/01/12	YES
Cover letter for questionnaires/consent	1	20/01/12	YES
Letter to responsible clinician of participant results/concerns	1	20/01/12	YES
Debriefing Sheet	1	20/01/12	YES
Brief Interventions Questions: Guidance Questions for Staff	1	20/01/12	YES
Summary newsletter for participating clinics/surgeries	N/A	N/A	YES
Research Flowchart	1	20/01/12	YES
Useful information and contact numbers	1	20/01/12	YES
Brief Interventions Leaflet			YES
Letter to Responsible Clinician	2	05/07/12	YES
Participant Invitation Letter	2	05/07/12	YES
Invitation to staff focus groups	2	05/07/12	YES

Participant Information Sheet	1	20/01/10	YES
Participant Information Sheet	2	05/07/12	YES
Participant Information Sheet: Staff Focus Group	2	05/07/12	YES
Protocol	1	20/01/12	YES
Questionnaire: Demographic Data	1	20/01/12	YES
Questionnaire: SC1-R	N/A	N/A	YES
Questionnaire: Audit	N/A	N/A	YES

Please reply to this letter confirming the expected start date and duration of the study. As part of the Research Governance Framework it is important that the Trust is notified as to the outcome of your research and as such we will request feedback once the research has finished along with details of dissemination of your findings. We may also request brief updates of your progress from time to time, dependent on duration of the study. Similarly, if at anytime details relating to the research project or research team change, the R&D department must be informed.

If you have any further questions regarding this or other research you may wish to undertake in the Trust please feel free to contact me again. The Trust wishes you success with your research.

Yours sincerely

Lead RM&G Manager –

CC:

DIRECTORATE OF RESEARCH & DEVELOPMENT

Director:

Assistant Director:

R&D Manager:

21/09/12

Dear Mrs. Katy Knott

Ref: CSP 96612
Title: **A prevalence study of alcohol consumption and adherence to self care behaviours of those with Type 2 diabetes; followed by a pilot study to develop and refine Brief Interventions for alcohol and consider what impact this would have on adherence to diabetes self care behaviours and explore whether this would be feasible to include in routine diabetes care.**
Project Status: **Approved**
End Date: **28/02/13**

I am pleased to confirm that with effect from the date of this letter, the above study has Trust Research & Development permission to commence at _____ NHS Trust. The research must be conducted in line with the Protocol and fulfil any contractual obligations agreed with the Sponsor. If you identify any issues during the course of your research that are likely to affect these obligations you must contact the R&D Office.

In order for the UHL Trust to comply with targets set by the Department of Health through the 'Plan for Growth', there is an expectation that the first patient will be recruited within 30 days of the date of this letter. If there is likely to be a problem achieving this target, please contact the office as soon as possible. You will be asked to provide the date of the first patient recruited in due course. In addition, the Title, REC Reference number, local target recruitment and actual recruitment for this study will be published on a quarterly basis on the ___ Trust external website.

All documents received by this office have been reviewed and form part of the approval. The documents received and approved are as follows:

Document Title	Version	Date	REC Approval
REC favourable opinion letter	N/A	24/07/12	N/A

Version 10, 24/04/2012

Interview Schedules/Topic Guides-Focus Group	1	20/01/12	YES
Letter of invitation to participant	1	20/01/12	YES
Cover letter for questionnaires/consent	1	20/01/12	YES
Letter to responsible clinician of participant results/concerns	1	20/01/12	YES
Debriefing Sheet	1	20/01/12	YES
Brief Interventions Questions: Guidance Questions for Staff	1	20/01/12	YES
Summary newsletter for participating clinics/surgeries	N/A	N/A	YES
Research Flowchart	1	20/01/12	YES
Useful information and contact numbers	1	20/01/12	YES
Brief Interventions Leaflet			YES
Letter to Responsible Clinician	2	05/07/12	YES
Participant Invitation Letter	2	05/07/12	YES
Invitation to staff focus groups	2	05/07/12	YES
Participant Information Sheet	1	20/01/10	YES
Participant Information Sheet	2	05/07/12	YES
Participant Information Sheet: Staff Focus Group	2	05/07/12	YES
Protocol	1	20/01/12	YES
Questionnaire: Demographic Data	1	20/01/12	YES
Questionnaire: SC1-R	N/A	N/A	YES
Questionnaire: Audit	N/A	N/A	YES

Please be aware that any changes to these documents after approval may constitute an amendment. The process of approval for amendments should be followed. Failure to do so may invalidate the approval of the study at this trust.

Undertaking research in the NHS comes with a range of regulatory responsibilities. Please ensure that you and your research team are familiar with, and understand the roles and responsibilities both collectively and individually.

Documents listing the roles and responsibilities for all individuals involved in research can be found on the R&D pages of the Public Website. It is important that you familiarise yourself with the Standard Operating Procedures, Policies and all other relevant documents which can be located by visiting

Version 10, 24/04/2012

The R&D Office is keen to support and facilitate research where ever possible. If you have any questions regarding this or other research you wish to undertake in the Trust, please contact this office. Our contact details are provided on the attached sheet.

This study has been reviewed and processed by the ▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓ ▓▓▓▓▓ Comprehensive Local Research Network ▓▓▓▓▓▓ using the Coordinated System for gaining Trust Permission (CSP). If you require any further information on the approval of this study please contact the ▓▓▓▓▓▓▓ office on ▓▓▓▓▓▓▓ making reference to the CSP number which is located at the top of this letter.

We wish you every success with your research.

Yours sincerely

▓▓▓▓▓▓▓▓▓▓▓▓▓▓

R&D Manager

Encs: .R&D Office Contact Information

Dear Katy,

RE: IRAS 96612 - A prevalence study of alcohol consumption and adherence to self-care behaviours of those with Type 2 diabetes; followed by a pilot study to develop and refine Brief Interventions for alcohol and consider what impact this would have on adherence to diabetes self-care behaviours and explore whether this would be feasible to include in routine diabetes care

Your study as detailed above has been assessed for eligibility to be considered for NIHR CRN support. I am pleased to inform you that your study has been deemed eligible for consideration for CRN support.

I have initialised the study onto the Portfolio Database and this has been given the number **UKCRN ID 12835 (DRN 723).**

In order to complete the study record and release it live, please complete and return the attached Minimum Data Set form.

You can find out more about the benefits of inclusion in the NIHR portfolio by following the link below:
http://www.crncc.nihr.ac.uk/about_us/processes/portfolio/benefits.htm

Kind regards

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please enter a short title for this project (maximum 70 characters)
Alcohol use in diabetic Type 2 population and Brief Interventions

1. Is your project research?

◉ Yes ○ No

---

2. Select one category from the list below:

○ Clinical trial of an investigational medicinal product

○ Clinical investigation or other study of a medical device

○ Combined trial of an investigational medicinal product and an investigational medical device

○ Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

○ Basic science study involving procedures with human participants

○ Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

○ Study involving qualitative methods only

○ Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

○ Study limited to working with data (specific project only)

○ Research tissue bank

○ Research database

If your work does not fit any of these categories, select the option below:

◉ Other study

2a. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

○ Yes   ◉ No

2b. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	○ Yes	◉ No
b) Will you be taking new human tissue samples (or other human biological samples)?	○ Yes	◉ No
c) Will you be using existing human tissue samples (or other human biological samples)?	○ Yes	◉ No

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3. In which countries of the UK will the research sites be located?(Tick all that apply)

☑ England

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1   96612/371927/13/751/15534

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☐ Scotland
☐ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

◉ England

◯ Scotland

◯ Wales

◯ Northern Ireland

◯ This study does not involve the NHS

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4. Which review bodies are you applying to?

☑ NHS/HSC Research and Development offices
☐ Social Care Research Ethics Committee
☑ Research Ethics Committee
☐ National Information Governance Board for Health and Social Care (NIGB)
☐ Ministry of Justice (MoJ)
☐ National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D offices, the CI must create Site-Specific Information Forms for each site, in addition to the study-wide forms, and transfer them to the PIs or local collaborators.

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5. Will any research sites in this study be NHS organisations?

◉ Yes   ◯ No

5a. Are all the research costs and infrastructure costs for this study provided by an NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC) or NIHR Research Centre for Patient Safety & Service Quality in all study sites?

◯ Yes   ◉ No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP).

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network (CRN) Portfolio? Please see information button for further details.

◉ Yes   ◯ No

If yes, NHS permission for your study will be processed through the NIHR Coordinated System for gaining NHS Permission (NIHR CSP) and you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form immediately after completing this project filter and before completing and submitting other applications.

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6. Do you plan to include any participants who are children?

◯ Yes   ◉ No

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7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

◯ Yes   ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of

identifiable tissue samples or personal information, except where application is being made to the NIGB Ethics and Confidentiality Committee to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes   ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes   ○ No

Please describe briefly the involvement of the student(s):
The study will be undertaken as part of a doctorate.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes   ○ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes   ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes   ◉ No

NOTICE OF SUBSTANTIAL AMENDMENT	

Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs).
The form should be completed by the Chief Investigator using language comprehensible to a lay person.

Details of Chief Investigator:

Work Address	
PostCode	
Email	
Telephone	
Fax	

Full title of study:	A prevalence study of alcohol consumption and adherence to self-care behaviours of those with Type 2 diabetes; followed by a pilot study to develop and refine Brief Interventions for alcohol and consider what impact this would have on adherence to diabetes self-care behaviours and explore whether this would be feasible to include in routine diabetes care
Lead sponsor:	
Name of REC:	
REC reference number:	12/EM/0238
Name of lead R&D office:	
Date study commenced:	08/10/2012
Protocol reference (if applicable), current version and date:	05/07/2012 version 2
Amendment number and date:	1, 08/10/2012

Type of amendment

(a) Amendment to information previously given in IRAS

⦿ Yes   ◯ No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

A18: participant information sheets for stage 1 will be sent out to participants, in some cases along with an invitation letter from

A27-1: in addition to already stated recruitment points the   research clinic lists and the list of individuals who have agreed to be contacted for research will be utilised, as staff at the Diabetes Centre will identify potential participants from this source.

A29: participant will first be approached by letter contact with information sheets for stage 1 being sent out to participants, in some cases along with an invitation letter from ▒▒▒▒▒▒▒▒▒▒

In line with the advice given by the REC board the information sheets are to be sent out in advance of potential participants attending their routine diabetes appointments, to allow time for consideration of whether to participate.

▒▒▒

(b) Amendment to the protocol

◉ Yes   ○ No

If yes, please submit <u>either</u> the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

protocol dated 05/07/2012 version 2 uploaded with changes highlighted in bold.

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

○ Yes   ◉ No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Is this a modified version of an amendment previously notified and not approved?

○ Yes   ◉ No

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.
If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.
If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

A18: participant information sheets for stage 1 will be sent out to participants, in some cases along with an invitation letter from ▒▒▒▒▒▒▒▒▒▒

A27-1: in addition the ▒▒▒▒▒▒▒▒▒▒ research clinic lists and the list of individuals who have agreed to be contacted for research will be utilised, as staff at the Diabetes Centre will identify potential participants from this source.

A29: participant will first be approached by letter contact with information sheets for stage 1 being sent out to participants, in some cases along with an invitation letter from ▒▒▒▒▒▒▒▒▒▒

In line with the advice given by the REC board the information sheets are to be sent out in advance of potential participants attending their routine diabetes appointments, to allow time for consideration of whether to participate.

To enable wider recruitment to the study the following additional recruitment points are to be added to the study to include: GP practices accessed through the Primary Care Research Network in ▒▒▒▒▒▒▒▒▒▒▒ participants recruited through the Research Clinics at ▒▒▒▒▒▒ Diabetes Centre; participants recruited through the mailing list at ▒▒▒▒▒▒▒▒▒▒ that have agreed to be contacted regarding research. Participants recruited through the Research Clinics will be sent a letter of invitation from the Diabetes Clinics to invite them to participate first(attached).

Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

Three new documents have been enclosed for use in recruiting participantsa: a GP invitation letter to invite surgeries to participate in the study; a practice briefing to inform them of the study details; and a letter of invitation to those on the Diabetes Research Centre contact lists to invite them to participate in the study.

List of enclosed documents

Document	Version	Date
Protocol	version 2	05/07/2012
GP invitation letter	version 2	05/07/2012
Practice Briefing	version 2	05/07/2012
Participant invitation letter diabetes research centre	version 2	05/07/2012

Declaration by Chief Investigator

1. *I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.*
2. *I consider that it would be reasonable for the proposed amendment to be implemented.*

This section was signed electronically by Mrs Katy Knott on 09/10/2012 16:35.

Job Title/Post:	Trainee Clinical Psychologist
Organisation:	
Email:	

Declaration by the sponsor's representative

I confirm the sponsor's support for this substantial amendment.

This section was signed electronically by ████████ on 10/10/2012 13:27.

Job Title/Post:	Associate Director (R&D)
Organisation:	
Email:	

06 November 2012

Dear Mrs Knott

Study title: A prevalence study of alcohol consumption and adherence to self-care behaviours of those with Type 2 diabetes; followed by a pilot study to develop and refine Brief Interventions for alcohol and consider what impact this would have on adherence to diabetes self-care behaviours and explore whether this would be feasible to include in routine diabetes care

REC reference: 12/EM/0238
Protocol number: N/A
Amendment number:
Amendment date: 10 October 2012
IRAS Project Number: 96612

The above amendment was reviewed at the meeting of the Sub-Committee held on 31 October 2012 by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Practice Briefing	2	05 July 2012
GP Invitation letter	2	05 July 2012
Letter of invitation to participant	2	05 July 2012
Protocol	2	05 July 2012
Notice of Substantial Amendment (non-CTIMPs)		10 October 2012

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

12/EM/0238:	Please quote this number on all correspondence

Yours sincerely

Chair

E-mail:

Enclosures: *List of names and professions of members who took part in the review*

Copy to:

CSP Ref: 96612
REC Ref: 12/EM/0238

29 November 2012

Dear Mrs Katy Knott

Re: Amendment to A prevalence study of alcohol consumption and adherence to self-care behaviours of those with Type 2 diabetes; followed by a pilot study looking at whether Brief Interventions for alcohol can reduce alcohol consumption in increasing to higher risk drinkers in individuals with Type 2 diabetes (12/EM/0238) Date of submission to REC: 10/10/2012

Sponsor's Unique Amendment Number: Amendment 1 dated 08/10/2012

Following review of the above amendment, has decided that they can accommodate this amendment.

Permission for this amendment is conditional upon permission being issued from the Research Site, .The amendment may then be immediately implemented within and under the existing NHS Permission. Please note that you may only implement changes that were described in the amendment notice or letter.

The current study documents relating to Participant Identification that have permission for use within the Trust are as follows:

Document Name	Version Number	Date
Practice Briefing	2	05/07/2012
GP Invitation Letter	2	05/07/2012
Letter of Invitation to participant	2	05/07/2012
Protocol	2	05/07/2012

Notice of Substantial Amendment (Non-CTIMP)	N/A	10/10/2012
REC Favourable Opinion	N/A	06/11/2012

Yours sincerely

RM&G Manager

Tel:
Email:

22/11/12

CSP Ref: 96612
REC Ref: 12/EM/0238
Portfolio Ref: To be confirmed
End date: 28/02/13

Dear Mrs. Katy Knott

I am pleased to confirm that ▓▓▓▓▓▓ has reviewed your research study titled a prevalence study of alcohol consumption and adherence to self-care behaviours of those with Type 2 diabetes; followed by a pilot study to develop and refine Brief Interventions for alcohol and consider what impact this would have on adherence to diabetes care using the Coordinated System for gaining NHS Permission (CSP) and gives approval for participant identification to be conducted within the Trust on the condition that the Trust suffers no costs as a result of this study being undertaken. Participants identified within ▓▓▓▓▓▓ will be invited to participate in this study being delivered by ▓▓▓▓▓▓ Unmet service support costs will be provided by the ▓▓▓▓▓▓ Comprehensive Local Research Network. Your research has been entered onto the Trust's Research Database.

Please reply to this letter confirming the expected start date and duration of the study. As part of the Research Governance Framework it is important that the Trust is notified as to the outcome of your research and as such we will request feedback once the research has finished along with details of dissemination of your findings. We may also request brief updates of your progress from time to time, dependent on duration of the study. Similarly, if at any time details relating to the research project or research team change, the R&D department must be informed. In particular, if additional GPs are invited to become Participant Identification Centres, other than those on the original list you supplied, please notify us at the R&D Office with a revised list for the Trust's consideration and approval before approaching them.

The documents receiving permission for use with Participant Identification within the Trust are as follows:

PIC DOCS ONLY	Version	Date	REC Approval
REC favourable opinion letter	N/A	24/07/12	N/A
REC amendment letter	N/A	06/11/12	N/A
Interview Schedules/Topic Guides-Focus Group	1	20/01/12	YES
Cover letter for questionnaires/consent	1	20/01/12	YES
Letter to responsible clinician of participant results/concerns	1	20/01/12	YES
Debriefing Sheet	1	20/01/12	YES

Brief Interventions Questions: Guidance Questions for Staff	1	20/01/12	YES
Summary newsletter for participating clinics/surgeries	N/A	N/A	YES
Research Flowchart	1	20/01/12	YES
Useful information and contact numbers	1	20/01/12	YES
Brief Interventions Leaflet	N/A	N/A	YES
Letter to Responsible Clinician	2	05/07/12	YES
Participant Invitation Letter	2	05/07/12	YES
Invitation to staff focus groups	2	05/07/12	YES
Participant Information Sheet	1	20/01/10	YES
Participant Information Sheet	2	05/07/12	YES
Participant Information Sheet: Staff Focus Group	2	05/07/12	YES
Questionnaire: Demographic Data	1	20/01/12	YES
Questionnaire: SC1-R	N/A	N/A	YES
Questionnaire: Audit	N/A	N/A	YES
Practice Briefing	2	05/07/12	YES
GP invitation letter	2	05/07/12	YES
Letter of invitation to participants	2	05/07/12	YES
Protocol	2	05/07/12	YES

If you have any further questions regarding this or other research you may wish to undertake in the Trust please feel free to contact me again. The Trust wishes you success with your research.

Yours sincerely

RM&G Manager

Tel:
Email:

CC: - Deputy Director of Public Health and Health Improvement, NHS

     – R&D Team leader, University Hospitals of   NHS Trust

DIRECTORATE OF RESEARCH & DEVELOPMENT

Director:

Assistant Director:

R&D Manager:

29 November 2012

Dear Mrs. Katy Knott

Ref:	**96612**
Title:	**A prevalence study of alcohol consumption and adherence to self care behaviours of those with Type 2 diabetes; followed by a pilot study to develop and refine Brief Interventions for alcohol and consider what impact this would have on adherence to diabetes self care behaviours and explore whether this would be feasible to include in routine diabetes care.**
Project Status:	**Approved**
End Date:	**28/02/2013**

Thank you for submitting documentation for the **Substantial Amendment (Amendment 1 dated 08/10/2012)** to the above study.

I confirm that the have acknowledged these changes.

The documents received are as follows:

Document Name	Version Number	Date
Practice Briefing	**2**	**05/07/2012**
GP Invitation Letter	**2**	**05/07/2012**
Letter of Invitation to participant	**2**	**05/07/2012**

Protocol	2	05/07/2012
Notice of Substantial Amendment (Non-CTIMP)	N/A	10/10/2012
REC Favourable Opinion	N/A	06/11/2012

Please be aware that any changes to these documents after approval may constitute an amendment. The process of approval for amendments should be followed. Failure to do so may invalidate the approval of the study at this trust.

Please ensure that all documentation and correspondence relating to this amendment are filed appropriately in the relevant site file.

Yours sincerely

Assistant Director

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Dear Georgia,

Regarding the study below. Apologies, but unfortunately I have just realised I have made a mistake with a document I previously supplied. I have had a look at the IRAS website, which advises that for non-substantial amendments, these can be done by contacting your REC committee via letter or email. I have noticed that I should have added a few words into a document I am going to be using, which from my understanding would be a non-substantial amendment. Can I just confirm this?

I have attached the document. The words highlighted in red are the additional words. The intention is for some questionnaires to be returned via each method (post or return to GP surgery), with the alternate option deleted accordingly. Please do not hesitate to contact me if you need clarifications or if this should be a substantial amendment.

Many thanks,

Katy Knott

30 January 2013

Mrs Katy Knott
Trainee Clinical Psychologist
Leicester Partnership Trust
Clinical Section, University of Leicester
104 Regent Road
Leicester
LE1 7LT

Dear Mrs Knott

Study title: **A prevalence study of alcohol consumption and adherence to self-care behaviours of those with Type 2 diabetes; followed by a pilot study to develop and refine Brief Interventions for alcohol and consider what impact this would have on adherence to diabetes self-care behaviours and explore whether this would be feasible to include in routine diabetes care**

REC reference: 12/EM/0238
Protocol number: N/A
Amendment number:
Amendment date: **20 January 2013**
IRAS project ID: **96612**

Thank you for your letter of 20 January 2013, notifying the Committee of the above amendment.

The Committee does not consider this to be a "substantial amendment" as defined in the Standard Operating Procedures for Research Ethics Committees. The amendment does not therefore require an ethical opinion from the Committee and may be implemented immediately, provided that it does not affect the approval for the research given by the R&D office for the relevant NHS care organisation.

Documents received

The documents received were as follows:

Document	Version	Date
GP Letter headed participant invitation	1	01 January 2013
Notification of a Minor Amendment		20 January 2013

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Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

12/EM/0238:	Please quote this number on all correspondence

Yours sincerely

~~Miss Georgie Copeland~~

Assistant Committee Co-ordinator

E-mail: ~~EMREDCommittee.EastMidlands-Northampton@nhs.net~~

Copy to: ~~Mr David Clarke, Leeds Partnership Trust~~

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Appendix J Demographic Table: Stage 1

Demographic factor	Diabetes Clinic (%)	Research list (%)	GP surgeries (%)	Total (%)
Gender:				
Male	46.4	57.6	63.4	57.1
Female	51.8	42.4	35.5	41.8
Other	1.8	0	1.1	1.1
Age group:				
<25	0	0	0	0
26-40	8.9	6.1	4.3	6.0
41-55	19.6	15.2	26.9	22.5
>56	71.4	78.8	68.8	71.4
Ethnicity:				
Indian	32.1	6.1	26.9	24.7
Pakistani	3.6	0	1.1	1.6
Bangladeshi	0	0	0	0
Any other Indian background	3.6	0	0	1.1
Caribbean	0	3.0	3.2	2.2
African	0	3.0	0	0.5
Any other Black background	0	0	0	0
White British	60.7	87.9	67.7	69.2
Any other White background	0	0	1.1	0.5
Chinese	0	0	0	0
Mixed ethnicity	0	0	0	0
Other	0	0	0	0
Marital status:				
Single	7.1	3.0	7.5	6.6
Co-habiting	1.8	9.1	5.4	4.9
Married	66.1	63.6	66.7	65.9
Divorced	14.3	9.1	7.5	9.9
Separated	0	0	2.2	1.1
Widowed	8.9	15.2	10.8	11.0
Other	1.8	0	0	.5
Employment:				
Full-time	32.1	15.2	35.5	30.8
Part-time	5.4	3.0	7.5	6.0
Retired	37.5	75.8	41.9	46.7
Unemployed	1.8	3.0	4.3	3.3
Self-employed	12.5	0	3.2	5.5
Student	0	0	0	0
Unable to work	7.1	3.0	4.3	4.9
Other	3.6	0	3.2	2.7

Appendix K Chronology of research process (CONSORT diagram)

Screened for eligibility n =18,470; Research List n=172; GP surgeries n=approx 17,600; Diabetes Clinic n=698

Excluded n =17,551; Research List n=78 did not meet inclusion criteria; GP surgeries n=16,544 did not meet inclusion criteria, n=456 excluded due to imposed limit of 200 per surgery; Diabetes Clinic n=473 did not meet inclusion criteria

Invited to participate in Stage 1 n=919; Research list n=94, GP surgeries n=600, Diabetes Clinic n=225

Participated n=279; Research List n=43 (unable to obtain reasons for non-participation); GP surgery n=117 (unable to obtain reasons for non-participation); Diabetes Clinic n=119 (reasons for non-participation: non-attendance (52), refusal (24), unable to read or write (11), cancelled (14), missed participant (5))

Analyzed n =182 Excluded from analysis n= 97 (reasons for exclusion included whole measures not completed (48), missing questions from measures (49))

Eligible to participate in Stage 2 and consented to being contacted n=21

Unable to make contact, unable to attend appointment or withdrew consent n=15

Attended BI appointment n=6

Provided follow-up data n=6

Analyzed n=6

Stage 1

Stage 2

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Appendix L Participant Information Sheet: Stage 1

University *of* Leicester

At your next appointment you may be asked to fill out two questionnaires, one about your alcohol consumption and one about your diabetes self care behaviours which includes things such as how often you check your blood glucose and if you are going to diabetes check-up appointments. Not much is known about how similar or different the drinking pattern of people with Type 2 diabetes is to that of the general population, and it is hoped that by taking part in this study you will help gather this information.

It is estimated that the two short questionnaires should take no more than seven minutes to complete and you will also be asked to complete a short form asking for some information such as your age, gender and ethnicity. After you have completed both questionnaires you are asked to hand them in at your appointment.

If you do not wish to take part in this study this will not affect your care as the research is being carried out by an independent Researcher from Leicester University. You have until your appointment to consider whether to take part. Feel free to talk to others about the study in the meanwhile. You will be given the option to consent to your care team being informed of your scores on the questionnaires, but can decline to do this if you wish to keep the information confidential. You will have a unique participant number that will mean no personal identifiable information will collected. There is a small chance that you may be asked to participate in part two of the study, which involves giving up half an hour of your time. There will be a consent form that accompanies the questionnaires where you are given the option to agree or decline to be contacted for the second stage. A letter with more details will be sent to you if this occurs.

It is hoped that the information from this study will help professionals working in diabetes care to know what level of support around alcohol to include in diabetes check up appointments. If you become distressed by the topics covered in the questionnaire support can be provided either by your care team or specialist agencies.

Please feel free to contact the main researcher, Katy Knott, with any further questions on kek9@le.ac.uk. In addition the results of the research will be available from June 2013, please feel free to contact the researcher for a summary of the result

Appendix M Participant Information Sheet: Stage 2

University *of* Leicester

<u>Participant Information Sheet</u>

A study of alcohol use and adherence to self care behaviours of people with Type 2 diabetes, and whether brief advice around alcohol would be useful and practical to include in routine diabetes check up appointments

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. The Researcher will answer any questions you have either by email or during your appointment. We suggest this should take around five to ten minutes. Feel free to talk to others about the study if you wish. The National Institute for Health Research Network has a website that answers lots of questions about participating in research (details provided at the end of this form).

This study aims to look at the usefulness and practicalities around including a brief advice around alcohol into the routine care offered to people who have diabetes. Two questionnaires will be used to look at alcohol use and key diabetes self-care behaviours such as following a good diet and attending check-up appointments.

Part 1

What is the purpose of the study?

The purpose of this study is to see if brief advice around alcohol could be helpful to include in diabetes appointments and would be feasible to fit into them. Some research suggests that alcohol could negatively affect motivation making us less likely to take care of our health. This study hopes to look into this and help improve the care provided for people with Type 2 diabetes. The study also forms part of an educational programme which will contribute towards a doctoral award.

Why have I been invited?

You were chosen for this study from your initial results on the alcohol screening questionnaire. Forty other individuals have been asked to take part in this bit of the study.

Do I have to take part?

It is up to you to decide to join the study. We will describe the study and go

through this information sheet. If you agree to take part it is asked that you contact the Researcher to confirm that you are able to make the appointment that has been scheduled for you. You have up to two weeks to consider whether to take part in the study. At the appointment you will be asked to sign a Consent Form. You are free to withdraw at any time without giving a reason. This would not affect the care you receive.

What will happen to me if I take part and what will I have to do?

If you agree to take part you will be asked to attend an appointment where you will once again be asked to fill out the questionnaires about your alcohol intake and your diabetes self care behaviours. You will then receive a 5-15 minute Brief Intervention; this will consist of brief information and advice around alcohol and its associated risks. This appointment should last no longer than half an hour and you will be reimbursed for your travel costs and refreshments will be provided. The same questionnaires will be sent out to you a month later to see if there are any changes in your alcohol use or diabetes self care. You will be asked to send these back in a provided stamped addressed envelope. The results from your questionnaires will be looked at to see if a Brief Intervention for alcohol could fit in with routine diabetes care and whether it has any impact on your diabetes self-care behaviours.

Looking at diabetes forums there is a lot of confusion around what is safe to drink for someone with diabetes. We want to see how realistic it is that the staff that you see at your regular diabetes check-up appointments could be giving a bit of advice and support around alcohol to you when you see them in your regular check up appointments.

What are the possible disadvantages or risks of taking part?

The risks involved in participating in this study include the potential for distress if you are concerned about your alcohol use. Support can be provided if you do feel distressed at any point. If you wish to receive further support around alcohol use after the study finishes then some numbers for support are included in Part 2 of this sheet, or you can ask the Researcher to inform your Responsible Clinician at your clinic or surgery that you need more support.

What are the possible benefits of taking part?

This study may support you by increasing your awareness around alcohol, however we cannot promise the study will help, but the information we get from this study may help improve the treatment available for other people with Type 2 diabetes who may find alcohol is an issue.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2 of this sheet.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

What if relevant new information becomes available?

If new information comes to light regarding Brief Interventions for alcohol, in particular if it is suggested that they could be of little support, this information will be made available immediately to GP surgeries and diabetes clinics to pass on to participants.

What happens if I don't want to carry on with the study?

If the study is stopped for any reason we will tell you immediately. If you withdraw from the study, we will destroy your identifiable data, but we will use the data collected up to your withdrawal.

What if there is a problem?

If you have any concerns about any aspects of this study, you should contact the Researcher who will do their best to answer any questions (kek9@le.ac.uk). If you remain unhappy and wish to complain formally, you can contact Leicester Partnership Trust customer services on 0116 295 0830 or complaints@lcrchs.nhs.uk for further details.

In the unlikely event that something does go wrong during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against Leicester Partnership Trust but you may have to pay your legal costs. The normal National Health Service complaints procedure will still be available to you.

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be anonymous and kept strictly confidential. Data will be collected by the Researcher and coded so that only the Researcher will be able to identify which questionnaires belong to which participant. Personal identifiable data will be destroyed securely after your second set of questionnaires have been sent to you. All anonymised information collected will be stored in a locked cabinet at Leicester University and will be kept securely for five years after research completion before being disposed of securely. The researchers, the

sponsor, regulatory bodies and the Research and Development department may need access to your anonymous data to review it and to monitor the quality of the research.

Involvement of Responsible Clinicians

When you sign the consent form you will be asked if you agree to the clinician responsible for your diabetes care to be informed of the results of your questionnaires. It may also be useful to inform them if you express any concerns about your alcohol use and want further support. This research is however being carried out be a researcher independent of your care team, therefore you can choose not to inform your care team of your participation or results.

What will happen to the results of the research study?

After the study has finished the results will be written up as part of a doctoral award and may also be published in scientific journals.   The results will also be available for you, from June 2013 onwards, to read if you wish; contact details are provided for you to request a summary of these.   You will not be able to be identified in any of these reports or publications.

Who is organising and funding the research?

The research is organised by Leicester University and is funded by Leicester Partnership NHS Trust and the National Institute for Health Research.

Who has reviewed the research?

The research has been reviewed by the University of Leicester, a group of healthcare service users and two independent reviewers working within the field of Diabetes care and research. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Northampton Research Ethics Committee. The study is also supported by the National Institute for Health Research.

Please feel free to contact the main researcher if there is anything that is not clear.

Appendix N Demographic Table: Stage 2

Demographic factor	Total of 6 participants
Gender:	
Male	5
Female	1
Age group:	
<25	0
26-40	0
41-55	3
>56	3
Ethnicity:	
Indian	0
Pakistani	0
Bangladeshi	0
Any other Indian background	0
Caribbean	0
African	0
Any other Black background	0
White British	6
Any other White background	0
Chinese	0
Mixed ethnicity	0
Marital status:	
Single	0
Co-habiting	2
Married	4
Divorced	0
Separated	0
Widowed	0
Other	0
Employment:	
Full-time	2
Part-time	0
Retired	4
Unemployed	0
Self-employed	0
Student	0
Unable to work	0

Appendix O Brief Intervention Pack

This is one unit...

For more detailed information on calculating units see - www.units.nhs.uk/

Half pint of regular beer, lager or cider

1 very small glass of wine(9%)

1 single measure of spirits

1 small glass of sherry

1 single measure of aperitifs

How many units did you drink today?

...and each of these is more than one unit

2 — A pint of "regular" beer, lager or cider

3 — A pint of "strong"/ "premium" beer, lager or cider

1.5 — Alcopop or a 275ml bottle of regular lager

2 — 440ml can of "regular" lager or cider

4 — 440ml can of "super strength" lager

3 — 250ml glass of wine (12%)

9 — Bottle of wine (12%)

Risk	Men	Women	Common Effects
Lower Risk	No more than 3-4 units per day on a regular basis	No more than 2-3 units per day on a regular basis	•Increased relaxation •Sociability •Reduced risk of heart disease (for men over 40 and post menopausal women)
Increasing Risk	More than 3-4 units per day on a regular basis	More than 2-3 units per day on a regular basis	***Progressively increasing risk of:*** •Low energy •Memory loss •Relationship problems
Higher Risk	More than 8 units per day on a regular basis or more than 50 units per week	More than 6 units per day on a regular basis or more than 35 units per week	•Depression •Insomnia •Impotence •Injury •Alcohol dependence •High blood pressure •Liver disease •Cancer

There are times when you will be at risk even after one or two units. For example, with strenuous exercise, operating heavy machinery, driving or if you are on certain medication.

If you are pregnant or trying to conceive, it is recommended that you avoid drinking alcohol. But if you do drink, it should be no more than 1-2 units once or twice a week and avoid getting drunk.

Your screening score suggests you are drinking at a rate that increases your risk of harm and you might be at risk of problems in the future.

What do you think?

NHS

What's everyone else like?
% of Adult Population

Population by Risk Category
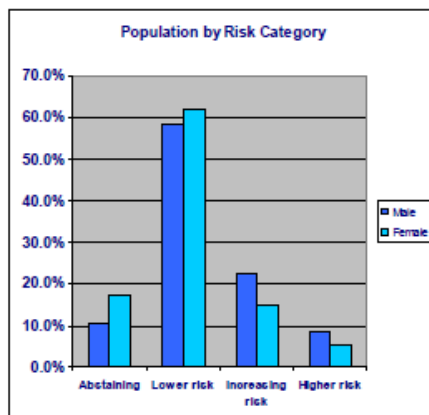
Making your plan
- When bored or stressed have a workout instead of drinking
- Avoid going to the pub after work
- Plan activities and tasks at those times you would usually drink
- When you do drink, set yourself a limit and stick to it
- Have your first drink after starting to eat
- Quench your thirst with non-alcohol drinks before and in-between alcoholic drinks
- Avoid drinking in rounds or in large groups
- Switch to low alcohol beer/lager
- Avoid or limit the time spent with "heavy" drinking friends

The benefits of cutting down
Psychological/Social/Financial
- Improved mood
- Improved relationships
- Reduced risks of drink driving
- Save money

Physical
- Sleep better
- More energy
- Lose weight
- No hangovers
- Reduced risk of injury
- Improved memory
- Better physical shape
- Reduced risk of high blood pressure
- Reduced risk of cancer
- Reduced risks of liver disease
- Reduced risks of brain damage

What targets should you aim for?
Men
Should not regularly drink more than 3–4 units of alcohol a day.
Women
Should not regularly drink more than 2–3 units a day

'Regularly' means drinking every day or most days of the week.
You should also take a break for 48 hours after a heavy session to let your body recover.

What is your personal target?

This brief advice is based on the **"How Much Is Too Much?"** Simple Structured Advice Intervention Tool, developed by Newcastle University and the Drink Less materials originally developed at the University of Sydney as part of a W.H.O. collaborative study.

University of Leicester

<u>Useful information and contact numbers</u>

The accompanying leaflet contains some figures that describe the levels of alcohol consumption recommended for the general population. However the Diabetes UK website suggests that people with Type 2 Diabetes should have no more than 2 units of alcohol a day for women and 3 units of alcohol a day for men.

Lots of research suggests that alcohol can have an impact on the amount people with Diabetes carry out key self-care behaviours. These include lessening motivation to follow a good diet, take medication and maintain safe blood sugar levels.

If you decide to change your drinking habits it might be helpful to think about why you want to make changes, and how you could go about doing this. If you have been drinking more than 10 units of alcohol a day it is not safe to stop drinking quickly. It's thought safe to reduce by no more than 1-2 units a day. If you have concerns about your alcohol use and don't feel able to talk about these in your appointment a list of useful numbers to get more support are included below.

Some useful numbers:

Community Alcohol Team
Drury House
0116 225 6350
worker is available to speak to on the telephone:
Monday, Tuesday and Thursday 12.30pm-5.00pm
Wednesday 1.30pm-5.00pm
Friday 12.30pm-4.30pm

Drinkline
The National Alcohol Helpline
0800 917 8282
Drinkline offers free, confidential information and advice on alcohol

Alcohol Advice Centre
Leicestershire Community Projects
Trust
0116 222 9545

Turning Point
Loughborough
01509 611111

Turning Point
Coalville
01530 830865

Appendix P Consent Form: Stage 2

<u>Consent Form</u>

Centre Number:
Study Number:
Patient Identification Number for this trial:
Title of Project: A feasibility study of the incorporation of Brief Interventions for alcohol into the routine care of individuals with Type 2 diabetes
Name of Researcher: Katy Knott

Please initial box
1. I confirm that I have read and understand the information sheet dated.................... (version............) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from Leicester University, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I agree to take part in the above study.

Name of Patient……………………. Date…………. Signature…………………………

Name of Person……………………. Date………….. Signature…………………………..
taking consent
When completed: 1copy for the participant; 1 for researcher; 1 (original) to be kept in medical notes

Appendix Q Descriptive statistics for the SCI-R and AUDIT

Descriptive Statistics

	N	Minimum	Maximum	Mean	Std. Deviation
meanSCIR	182	2.00	4.83	3.3856	.60996
AUDIT	182	0	17	2.70	3.322
totalSCIR	182	25	96	59.85	15.193
Valid N (listwise)	182				

Appendix R Histograms of distribution of total SCIR and AUDIT scores

Histogram

Mean = 2.7
Std. Dev. = 3.322
N = 182
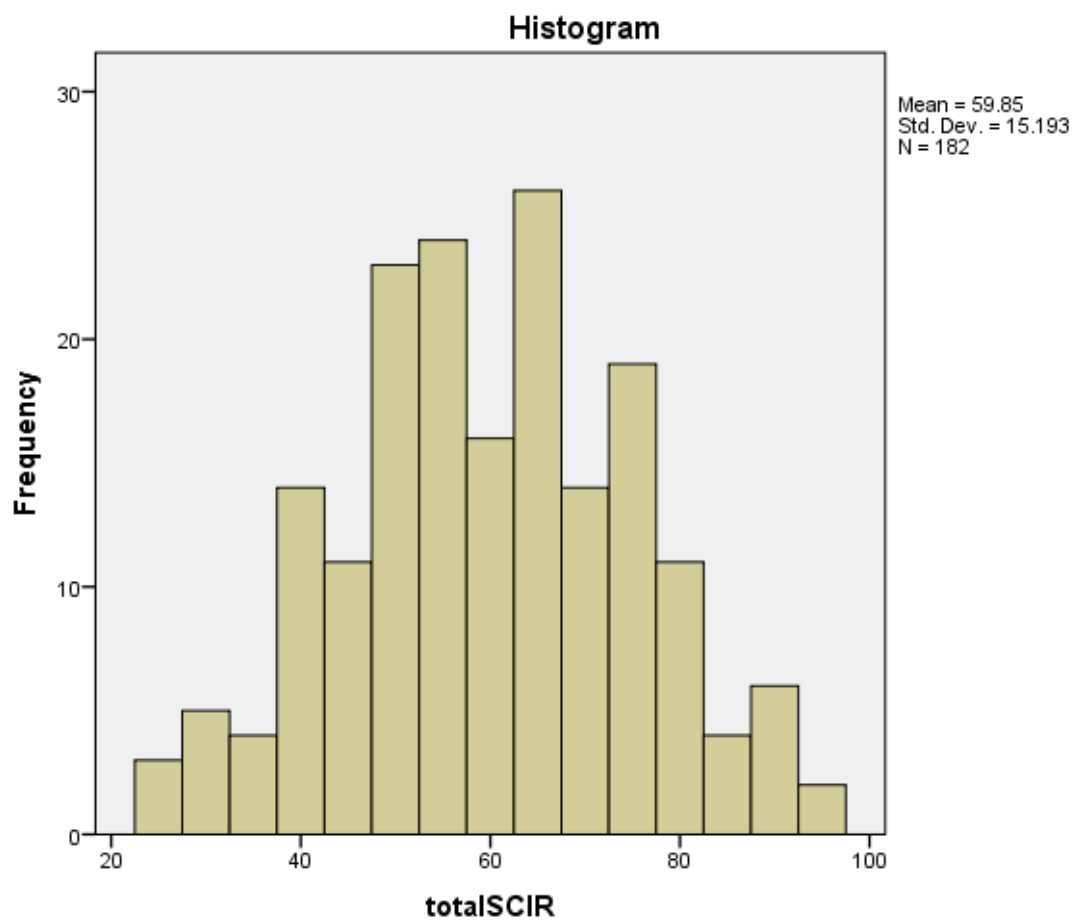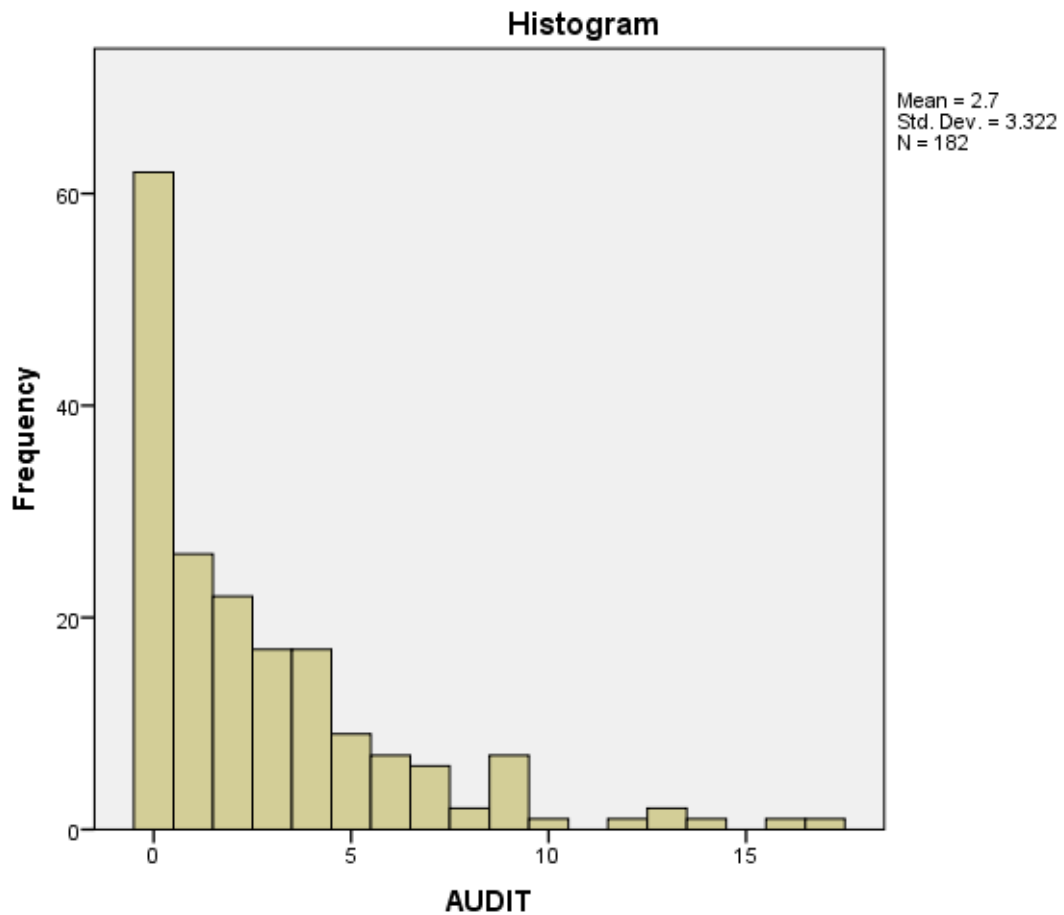
Appendix S Chi-Squared analysis

AUDITincreasinghigher

	Observed N	Expected N	Residual
yes	16	38.2	-22.2
no	166	143.8	22.2
Total	182		

Test Statistics

	AUDITincreasinghigher
Chi-Square	16.352[a]
df	1
Asymp. Sig.	.000

a. 0 cells (0.0%) have expected frequencies less than 5. The minimum expected cell frequency is 38.2.

Appendix T Spearman's Rank Order Correlation analysis

Correlations

			totalSCIR	AUDIT
Spearman's rho	totalSCIR	Correlation Coefficient	1.000	-.275[**]
		Sig. (2-tailed)	.	.000
		N	182	182
	AUDIT	Correlation Coefficient	-.275[**]	1.000
		Sig. (2-tailed)	.000	.
		N	182	182

**. Correlation is significant at the 0.01 level (2-tailed).

Appendix U Analysis of Variance analysis

ANOVA

totalSCIR

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	412.113	2	206.056	.892	.412
Within Groups	41368.882	179	231.111		
Total	41780.995	181			

Appendix V T-test analysis

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means							
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
AUDIT	Equal variances assumed	14.914	.000	3.761	178	.000	1.826	.486	.868	2.785
	Equal variances not assumed			4.070	169.578	.000	1.826	.449	.940	2.712

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Appendix W Wilcoxon Signed Ranked Test analysis

	postAUDIT - preAUDIT	postSCIR - preSCIR
Z	-1.160[b]	-1.483[c]
Asymp. Sig. (2-tailed)	.246	.138

Appendix X Scatter plot diagram of pre-intervention SCI-R and AUDIT scores
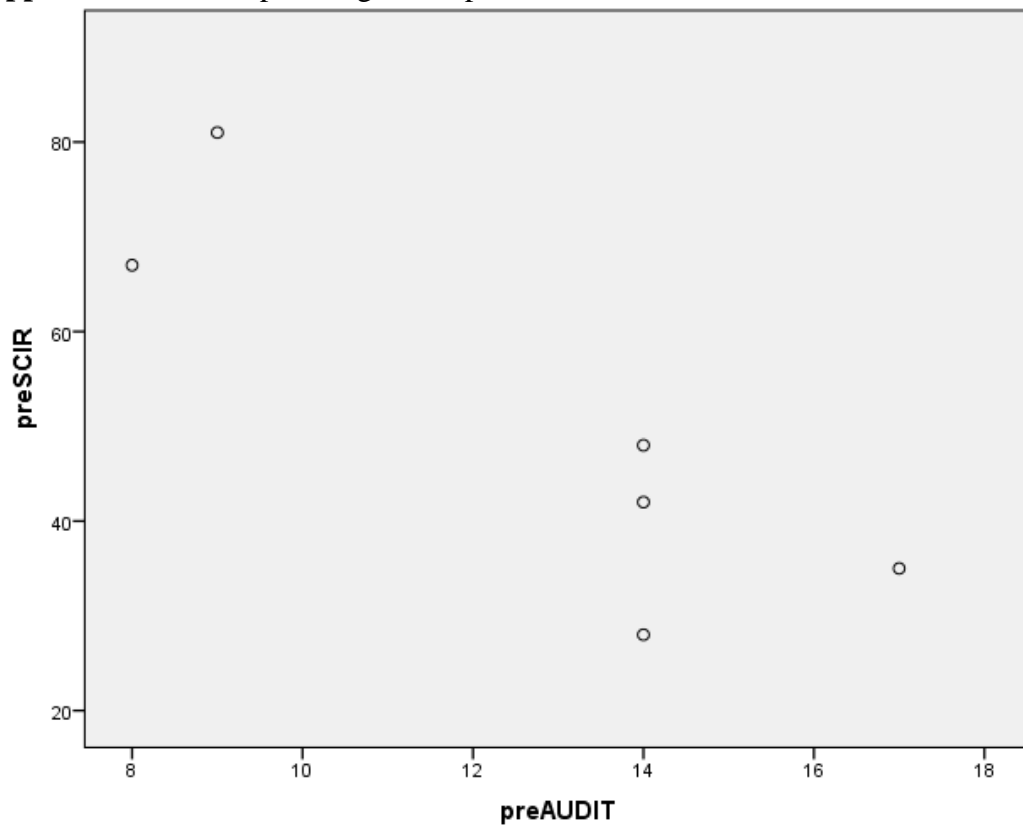
Scatter plot diagram of post-intervention SCI-R and AUDIT scores
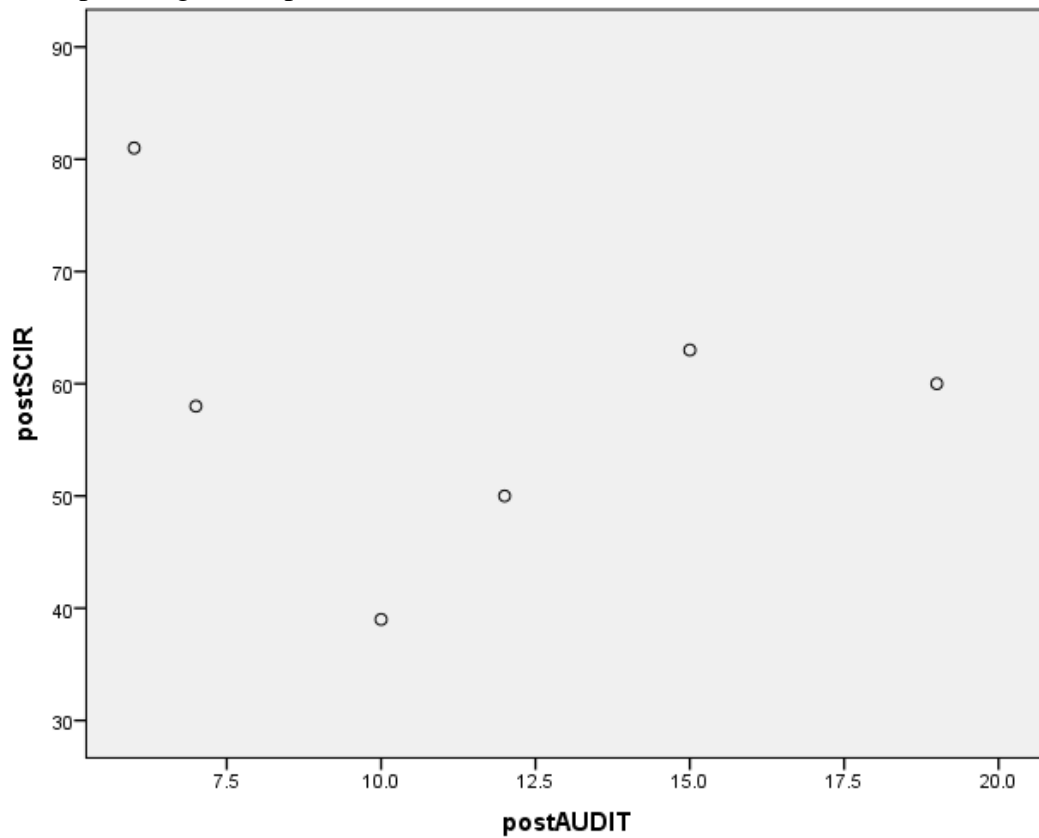
Appendix Y Spearman's Rank Order Correlation analysis

Correlations

			preAUDIT	postAUDIT	preSCIR	postSCIR
Spearman's rho	preAUDIT	Correlation Coefficient	1.000	.880[*]	-.759	-.152
		Sig. (2-tailed)	.	.021	.080	.774
		N	6	6	6	6
	postAUDIT	Correlation Coefficient	.880[*]	1.000	-.657	-.086
		Sig. (2-tailed)	.021	.	.156	.872
		N	6	6	6	6
	preSCIR	Correlation Coefficient	-.759	-.657	1.000	.543
		Sig. (2-tailed)	.080	.156	.	.266
		N	6	6	6	6
	postSCIR	Correlation Coefficient	-.152	-.086	.543	1.000
		Sig. (2-tailed)	.774	.872	.266	.
		N	6	6	6	6

*. Correlation is significant at the 0.05 level (2-tailed).

Appendix Z Epistemological position of the Researcher

The Researcher approached the study from a positivist stance, with the assumption that behaviour could be observed and empirically measured, using validated psychometric measures. The approach to the study was to focus upon measurable behaviour such as alcohol consumption and self-care, examining causal relationships and correlations.

Appendix AA Guidelines for target journal for literature review

CLINICAL PSYCHOLOGY REVIEW

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ISSN: 0272-7358

DESCRIPTION

Clinical Psychology Review publishes substantive reviews of topics germane to **clinical psychology.** Papers cover diverse issues including: psychopathology, psychotherapy, behavior therapy, cognition and cognitive therapies, behavioral medicine, community mental health, assessment, and child development. Papers should be cutting edge and advance the science and/or practice of clinical psychology.

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It is important that the file be saved in the native format of the wordprocessor used. The text should be in single-column format. Keep the layout of the text as simple as possible. Most formatting codes will be removed and replaced on processing the article. In particular, do not use the wordprocessor's options to justify text or to hyphenate words. However, do use bold face, italics, subscripts, superscripts etc. When preparing tables, if you are using a table grid, use only one grid for each individual table and not a grid for each row. If no grid is used, use tabs, not spaces, to align columns. The electronic text should be prepared in a way very similar to that of conventional manuscripts (see also the Guide to Publishing with Elsevier: http://www.elsevier.com/guidepublication). Note that source files of figures, tables and text graphics will be required whether or not you embed your figures in the text. See also the section on Electronic artwork.
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If there is more than one appendix, they should be identified as A, B, etc. Formulae and equations in appendices should be given separate numbering: Eq. (A.1), Eq. (A.2), etc.; in a subsequent appendix, Eq. (B.1) and so on. Similarly for tables and figures: Table A.1; Fig. A.1, etc.

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A concise and factual abstract is required (not exceeding 200 words). This should be typed on a separate page following the title page. The abstract should state briefly the purpose of the research, the principal results and major conclusions. An abstract is often presented separate from the article, so it must be able to stand alone. References should therefore be avoided, but if essential, they must be cited in full, without reference to the reference list.

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