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A pilot randomised controlled trial of a pre-consultation web-based intervention to improve the care quality and clinical outcomes of diabetes outpatients (DIAT): a protocol

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ABSTRACT

Introduction: Diabetes is a chronic condition associated with many long-term complications. People with diabetes need to actively manage their condition, which can be complex. In consultations with health care professionals, patients receive advice about their diabetes but do not always discuss things which concern them, perhaps because of perceived limited time or embarrassment. We want to test a 'pre-consultation' intervention in which the patient is supported by a Health Care Assistant to complete a web-based intervention aimed at producing an agenda to help them to identify important areas for discussion in the consultation. Use of this agenda may enable the patient to play a more active role in that consultation and consequently become more confident, and hence more successful, in managing their condition.

Methods and Analysis: In this pilot randomised controlled trial, 120 people with diabetes will be randomised with equal allocation to receive the intervention or usual clinical care. The primary outcome is reduction in glycosylated haemoglobin (HbA1c). Secondary outcomes are patient reported communication, enablement, self-care activity, diabetes-dependent quality of life, empowerment, satisfaction, health-related quality of life, and resource use. The aim of the pilot study is to estimate parameters to inform the design of the definitive trial. Follow-up on quantitative outcomes will be at three and six months. A nested qualitative study will collect data on the patients' experiences of producing an agenda. Resource use data and medication use will also be collected via a review of medical records for a sample of participants.

Ethics and dissemination: Approval was granted by the NHS Research Ethics Committee North West – Preston (13/NW/0123). Dissemination will include publication of both quantitative and qualitative findings, and experience of public involvement in peer reviewed journals. Results will also be disseminated to trial participants via workshops led by lay co-applicants.

Trial Registration: ISRCTN75070242

Article summary:

Article focus:

This paper describes a protocol for a pilot randomised controlled trial of a pre-consultation web-based intervention to enable patients with diabetes to produce their own agenda for a consultation with their Diabetologist.

Key messages:

A pre-consultation intervention in which the patient is supported by a Health Care Assistant to complete a web-based intervention will facilitate the production of 'their agenda' to help them to identify important areas for discussion in the consultation.

Combining both trial and qualitative research methods ensures that the 'active ingredients' of the intervention are identified and explored, which will enable estimate parameters to inform the design of a definitive trial.

Involving patients as collaborators ensures that this research deals explicitly with patients' information needs thus increasing the probability of the DIAT intervention being taken up in practice.

Strengths and limitations:

This study addresses areas identified as requiring more research in the 2013 Cochrane review of computer based diabetes self-management interventions for adults with Type 2 diabetes, which identified that interventions may have a small effect on blood glucose, but no benefits to cognitive, behavioural or emotional outcomes. The intervention is grounded in real-world patient experience, and pragmatically designed to be scaled up for a definitive trial and use in practice, but a potential limitation is that the follow up period may not be of a long enough to demonstrate a reduction in HbA1c.

INTRODUCTION

Diabetes will affect an estimated 439 million people globally by 2030, with an estimated 2.5 million in the UK [1]. Diabetes is a chronic disease, associated with a number of serious complications, and the costs of treating a person with diabetes rise by 60-90% as vascular problems progress [2]. Up to 80% of the NHS's £9.8bn annual UK expenditure on diabetes is spent on treating complications [3].

Diabetes is largely monitored and managed by patients themselves [4]. Self-management is complex involving, among other things, self-monitoring, behavioural change, medication management and a rigorous lifestyle regimen. Advice from professionals is vital to self-management, improving patients' ability to cope with their illness. Effective consultations are associated with empowerment, positive behaviour change and improved diabetes outcomes [5-9]. However, consultations with diabetologists are infrequent and patients often do not take full advantage of their time with their clinician [10]. They may feel embarrassed, rushed, or simply have forgotten some of the urgent problems they encountered since their previous consultation. Patients with Type 1 and Type 2 diabetes attending two diabetes centres in England perceived that they were not commonly questioned about sensitive aspects of their condition, such as erectile dysfunction and gastroparesis [11]. A UK service evaluation identified that health professionals, including diabetologists, felt competent in identifying patients' psychological issues but less knowledgeable and skilled in handling them [12]. Thus, methods to improve the quality of consultations in terms of the ability of the patient to discuss issues that concern them, understand information, and remember and follow advice, are consistently sought.

A systematic review found that the most common methods used to improve the quality of consultations are question checklists and patient coaching delivered immediately before consultations, and that information-seeking behaviour and patient satisfaction were most improved by combining coaching with written material [13]. Greenfield's 1988 [14] study using a review of medical records, a treatment algorithm and a behaviour change strategy, improved both patient participation in the consultation and glycaemic control. A more recent systematic review of computer

based diabetes self-management interventions for adults with Type 2 diabetes identified 16 randomised controlled trials, but was unable to distinguish between those that were set in primary care, outpatients or community settings [15]. The reviewers concluded that diabetes self-management interventions may have a small effect on blood glucose, with mobile 'phone based interventions having a greater impact than computer- based interventions, and no evidence of benefits to cognitive, behavioural or emotional outcomes. In conclusion, they were unable to discern the active ingredients or optimal 'dose' of the interventions.

A relatively inexpensive intervention has been developed by Cegala et al., evolving from an instruction booklet, to booklet plus coaching, to a web-based training module (http://patcom.jcomm.ohio-state.edu/). Cegala et al [16] identified that effective communication involves patients: *presenting* detailed information about how they are feeling; *asking* questions if desired information is not provided; *checking* understanding of information that is given to them; and *expressing* any concerns about the recommended treatment. This 'PACE' system has shown promise in oncology [17], has an outcome measure for communication [18], and can easily be tailored for use by people with diabetes.

The intervention has been designed to facilitate the articulation of patients' often unvoiced agendas [16, 18-25] which arise from their continual efforts to manage their conditions [26, 27]. Discussion of these agendas enables patients to manage their condition more effectively [7, 28-30], which includes better adherence [31, 32]. The PACE intervention has been modified specifically for diabetes (as PACE-Diabetes or PACE-D) by the DIAT Project Team. PACE-D is a web-based tool, designed to be completed by a patient before a clinic appointment. In this study the appointment is with a consultant diabetologist.

A trained health care assistant (HCA) will facilitate the use of the PACE-D tool, with the aim of assisting patients to identify the things that they wish to discuss with the diabetologist (i.e., their 'agenda') in the clinical consultation. The intervention takes approximately 20 minutes to complete, and consists of a series of open and closed questions, prompts, and a list of possible concerns that people with diabetes have identified (e.g., 'increased thirst' or 'depression'). On completion, a concise agenda

will automatically be produced, which the patient will take into their consultation with a diabetologist, and which may be used subsequently (i.e., in discussions with the GP or practice nurse, and to guide self-management).

PACE-D aims to enable patients to identify their agenda for discussion with the diabetologist, improving communication and empowering patients to be more pro-active at managing their diabetes, potentially leading to improved clinical and quality of life outcomes. The intervention appears to be a simple and relatively inexpensive tool but requires a rigorous test of its efficacy and cost-effectiveness. Piloting the PACE-D intervention and agenda with people with diabetes could provide improvements in communication, blood glucose management, enablement, self-care, medication use and quality of life, with little impact on cost or clinic time. We will measure enablement and patient perceptions of the effectiveness of the consultation, both perceived as crucial to effective diabetes control [28].

The aim of this pilot study is to obtain the necessary information for the planning of a future definitive trial to assess the clinical and cost effectiveness of a pre-clinic intervention specifically for diabetes.

The primary objective of this pilot study is to test the feasibility of running a randomised controlled trial of a pre-consultation web-based intervention to improve the care quality and clinical outcomes of people with diabetes.
Secondary objectives are to determine:

- The likely success of recruitment strategies.
- The acceptability of the research plan to proposed participants and allow for the estimation of likely participation and attrition rates.
- The data that will be useful for estimating the required sample size for a full trial.
- The training requirements of those clinic staff tasked with implementing the intervention.
- Resource use, e.g. the use of staff, required to provide the intervention and usual care.
- A preliminary estimate of the cost of the intervention.

- The validity and responsiveness of quality-of-life outcome measures in the patient group (including generic preference-based measures).
- The practicality and accuracy of using alternative methods of data collection for service and resource use (i.e. patient-report/review of medical records).

Patient and Public Involvement

Patient and Public Involvement (PPI) is fundamental to all aspects of this research. The research question was generated from a research prioritisation exercise, undertaken by the NIHR Collaboration for Leadership in Applied Health Research and Care in the South West Peninsula (PenCLAHRC) with active involvement from the Peninsula Patient and Public Involvement Group (PenPIG).

People with diabetes identified the research topic, and suggested that outpatient clinic appointments are pressured times, where health professionals can overlook issues that are worrying patients or where patients can feel inhibited from voicing their concerns. The same topic was identified by a diabetes specialist nurse (DSN) at a comparable professional workshop.

A project team was convened and a scoping exercise undertaken to assess what is known about the problem, and members of PenPIG discussed the existing research and perceptions of current and desired future clinic consultations. Two members of PenPIG who have diabetes joined the research team as co-applicants on this proposal. They also have representative roles within the local Diabetes Research Network and Devon Diabetes Service Strategy Implementation Group. Supported by a designated PPI Research Fellow, these two co-applicants have co-written the study documentation, and will assist in the analysis of the data, and the dissemination of the research results to both lay and professional audiences. They are members of the project management team and will assist in training the HCAs.

If the findings of the pilot indicate feasibility, there will be patient and public co-applicants on the full trial proposal which will be submitted to an appropriate source of funding. Members of the public involved in this pilot will be paid travel expenses and receive a payment in recognition of their contribution to the research.

METHODS

Trial Design

The pilot trial is a pragmatic pilot randomised controlled trial. The outcomes were chosen and the intervention designed during the development phase of the study (see Discussion).

[Insert figure 1 here]

Participants and study setting

The pilot trial will recruit 120 patients attending diabetes outpatient clinics at two hospitals in Devon, South West England, which treat people from both urban and rural settings. In 2010/11 these two diabetes centres undertook approximately 9,000 new appointments and 12,000 follow up appointments. People with a range of diabetes complications and co-morbidities will be included in the pilot, and the experiences gained will inform the inclusion and exclusion criteria of the larger trial. Although the intervention might potentially have benefit for all consultations (including those in primary care), benefit is likely to be greater in secondary care where typically more issues and problems are discussed. Eligible patients are adults with Type 1 or type 2 diabetes mellitus who are due to attend outpatient appointments with a diabetologist. Participants are aged 18 or over and have basic spoken or written English (to complete outcome measures). Women with pre-existing or gestational diabetes and people receiving insulin pump therapy are excluded.

Recruitment of patients

The study sample comprises people with diabetes who are due to attend a general diabetes clinic appointment at the Macleod Diabetes and Endocrine Centre at the Royal Devon and Exeter Hospital, Exeter, or the Medical Outpatients Department at Derriford Hospital, Plymouth. Potential participants will be identified from the clinic lists of participating consultant diabetologists by a research nurse at each location. Patients who express an interest in participating in the trial will be sent an information sheet. A research nurse will telephone each potential participant after a

minimum of one week, discuss any questions that the patient may have and establish if they are willing to participate. The nurse will then send a consent form and baseline questionnaires to those willing to take part. Following receipt of informed written consent and the completed baseline questionnaires, participants will be randomised to receive either the intervention or usual care (control), as detailed below.

Intervention

In a 20-minute session immediately preceding the clinic appointment, a trained HCA will help the patient to complete the PACE-D tool (the aim being for the patient to identify and produce their own agenda for the consultation). After the intervention, the patient will proceed to the clinical consultation, in which the printed output from the PACE-D intervention will act as an agenda for the consultation. Because of the nature of the intervention and the production of an agenda, it will not be possible to blind health professionals or patients to trial allocation. With consent, ten participants across the two sites will be audio-recorded as they use the PACE-D tool, for qualitative analysis.

Control

This comprises clinical care normally given by the diabetologist in outpatients clinics.

Outcomes

Primary Outcome Measure

The primary outcome measure is glycosylated haemoglobin (HbA1c) [33], a measure of glycaemic control. HbA1c levels will be measured within four weeks of each assessment (i.e., at baseline, three months and six months), and will be retrospectively obtained from participants' medical records.

Secondary Outcome Measures

Secondary outcome measures (patient self-reported rating scales) will be measured at all three time points. The rating scales will be sent to all participants with instructions for completion and a pre-paid return envelope. In addition, participants will be asked to document their current medication at each time point, and the

number and type of contacts with primary and secondary care practitioners during the study. Those in the treatment arm will also be asked at six months about their experience of using the PACE-D tool and the utility of producing 'their agenda'.

Patient self-reported outcome measures:

Audit of Diabetes-Dependent Quality of Life-19: Developed to measure an individual's perception of the impact of diabetes on their quality of life [34], this tool has 2 overview items and 19 individual domains (e.g., working life, holidays, physical appearance, etc). For each domain the respondent reports the *impact* of diabetes on their quality of life (on a 5 point scale, scored from -3 to 1 with higher scores indicating greater impact) and the *importance* of the domain (on a 4 point scale score from 0 to 3 with higher scores indicating greater importance). The quality of life score for each domain is calculated by taking the product of the impact and importance scores with scores ranging from -9 (maximum negative impact of diabetes) to +3 (maximum positive impact of diabetes). The *average weighted impact* score is calculated as the mean across the domain scores. The Patient Report of Outcomes Measure Group, Oxford [35] recommends the use of ADDQoL as their preferred diabetes specific measure.

Client Services Receipt Inventory: Originally developed for collecting cost-related information for people with mental health problems over a given period (usually the past six or twelve months) [36], this is a long-established, and widely adapted questionnaire. It collects retrospective information about the interviewee's use of health and social care services, home and employment situation, as well as income and benefits. We will pilot a simplified version of this questionnaire, tailored for diabetes and capturing resource use over a three month period, for intended use in the main trial.

Diabetes Empowerment Scale-Short Form: This scale was developed in the USA to measure diabetes related psychosocial self-efficacy [37, 38]. This eight item scale, derived from a behaviour change model, employs a 5 point Likert scale (*strongly disagree* (1) to *strongly agree* (5)). An overall score for the DES is calculated by taking the mean of the item scores.

Diabetes Self-Care Activity Measure: This 11-item instrument is a self-reported questionnaire of diabetes self-management which includes five aspects (activities) of the diabetes regimen [39, 40]. Questions for general diet (2 items), specific diet (2 items), exercise (2 items), blood glucose testing (2 items) and foot care (2 items), use an 8 point Likert scale (from 0-7) to record the number of days in the past week that the activity was undertaken. The overall score for each activity is calculated as the mean of the two items. Smoking (during the past 7 days), is recorded as yes or no; with smokers additionally reporting the number of cigarettes smoked on an average day.

Diabetes Treatment Satisfaction Questionnaire - Status and Change Versions: The Diabetes Treatment Satisfaction Questionnaire (Status, DTSQ(S)), was developed to measure patient satisfaction with diabetes treatment [41, 42]. The DTSQ(S) consists of six items to assess treatment satisfaction and two items to capture patient perceived hypoglycaemia/ hyperglycaemia. The DTSQ(S) items are scored on a Likert scale from 0 to 6 (0= *very dissatisfied*, 6=*very satisfied*). A total score is created as the sum of scores across the treatment satisfaction items (possible score from 0 to 36). In response to concerns about ceiling effects, where high baseline scores provide little opportunity to register change at follow up, the authors produced the DTSQ 'change' version (DTSQ(C)), which contains the same items, but asks patients to consider their satisfaction with current treatment compared with their previous treatment [43]. DTSQ(C) items are scored on a scale from -3 to 3 (-3=*less satisfied now*, 3= *more satisfied now*, with a midpoint of 0 reflecting no change). The total score is again calculated by summing the scores on the treatment satisfaction items, with the range of possible values from -18 to 18. Both versions will be used in order to capture initial perceptions and any change at follow up.

EuroQoL (EQ-5D-5L): The original EQ-5D is a generic measure for valuing and describing health. It defines health in terms of: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, and uses a 3 point Likert scale (*no problem*, *some problem*, *extreme problem* [44]). EQ-5D health states, defined by the EQ-5D descriptive system, may be converted into a single summary index by applying a formula that essentially attaches values (also called weights) to each of the levels in each dimension. The Patient Report of Outcomes Measure Group, Oxford [35] recommends the use of EQ5D as their preferred generic measure in combination

with a disease specific instrument. However, this instrument has also been found to suffer from ceiling effects, and a 5 level version has been developed (EQ-5D-5L), which uses a 5 point Likert scale (*no problem*, *slight problem*, *moderate problem*, *severe problem*, *extreme problem*) and has demonstrated increased reliability and sensitivity [45].

Patient Enablement Instrument: Developed to measure patient enablement after a consultation with a physician, the PEI contains six items with a 4 point Likert scale: *not applicable/same or less* (0); *better/more* (1); *much better/much more* (2) [46]. The total score is the sum of scores across the items (possible range of scores is 0 to a maximum score of 12). Haughney et al [47] have subsequently modified the opening statement to capture perspectives on treatment specifically, and this version will be used.

Patient Report of Communication: Developed to measure communication in conjunction with the PACE tool, this instrument comprises eleven questions about perceived communication, with two items for each of the four PACE skills, two additional items for the patient's ability to state their preferences and a global item about the consultation [18]. It uses a 5 point Likert scale that captures aspects of doctor-patient communication as *never* (1), *not very often* (2), *sometimes* (3), *usually* (4) and *always* (5). Mean scores will be calculated for each PACE skill and across all 11 items. This instrument has been shown to be reliable in cancer patients and those undergoing surgery [18].

Participant timeline

[Insert figure 2 here]

Sample size

As this is a pilot study, comparison of the outcomes between the trial arms is not a major objective and the study is not powered to do this. We aim to recruit 120 patients, 60 at each site. At least six clinic 'sessions' (i.e., the period of time in which a clinic is held within the outpatients department, usually in the morning or afternoon, when 8-15 patients are seen by their Consultant) at each site will be required.

An objective of the pilot study is to estimate the standard deviation for continuous outcomes to be used in the definitive trial as this will facilitate the sample size calculation for that study. We anticipate that at least half of the participants (i.e., sixty) will provide the follow-up data at six months. Sixty patients are sufficient to estimate a standard deviation to within 22% of its true value based on the upper bound of the 95% confidence interval.

The study will also estimate the percentage of eligible subjects that participate and the percentage of participants that are successfully followed up. If the true percentage of participants that provide follow-up data at six months is 50%, this study will be able to estimate this with a margin of error of +/-13% based on a 95% confidence interval assuming participants from a given clinic session are no more likely to drop out than those from another.

Randomisation

An independent statistician based at the Peninsula Clinical Trials Unit (PenCTU) will generate the randomisation list, using computer-generated random numbers. Randomisation will be stratified by clinic session.

Randomisation will be achieved by means of an automated web-based system created by a PenCTU data programmer in conjunction with the independent statistician and accessed by a separate member of PenCTU staff on receipt of the completed consent form. Consented participants will be allocated with equal probability to receive PACE-D or usual clinical care, using randomly permuted blocks of varying size to generate the allocation sequence and achieve balance in the numbers of participants allocated to each group.

Following randomisation, PenCTU will notify participants by standard letter about the arrival time for their clinic appointment. Those in the intervention arm will be notified that they are required to arrive 30 minutes early, while those in the control arm will be notified that they are *not* required to arrive early.

Statistical methods

The main aim of this pilot study is to estimate parameters that will ultimately inform the design of the main trial. The participation rate will be calculated as the

percentage of eligible subjects that are randomised, with 95% confidence intervals. The loss to follow-up rate will be reported at three months and six months with 95% confidence intervals. The standard deviation will be reported with 95% confidence intervals for the primary outcome. Other parameters to be reported include mean duration of the clinic conversation in each trial arm.

In ancillary analyses, baseline characteristics will be reported using percentages for categorical data, and means and standard deviations (or medians and inter-quartile ranges) for quantitative data. The trial arms will be compared at three and six months using the *t*-test for quantitative outcomes and the Chi-squared test for binary outcomes. Linear and logistic regression respectively will be used to adjust comparisons for baseline scores on the outcome. There will be no interim analyses, nor stopping rules applied. Missing data will not be imputed.

Qualitative methods

Ten intervention sessions will be audio-recorded with the participants' consent, to explore how participants utilise the PACE–D intervention and the amount of assistance that they require from the HCA in order to complete their agenda form.

In addition, approximately thirty clinical consultations across both trial arms and study sites will be audio-recorded, with the consent of both the participants and their diabetologist. Maximum variance sampling will be used, so that any impact of variables of interest (i.e., patient age, clinician grade, or clinic site) can be explored. Recording consultations is crucial to understanding the mechanism that underlies the impact of the production of an agenda on the clinical consultation, and its subsequent utilisation in practice, when compared with usual care. Hence we will report on the fidelity of the intervention, content of the consultation, context for the use of the agenda, and any impact on the consultation.

Semi-structured interviews will also be conducted with a sample of thirty participants across both trial arms and research sites, after participation in the trial has been completed and in order to examine aspects of intervention and participants' experiences of diabetes consultations in more depth [48]. With participants' consent, these interviews will be audio-recorded and will explore: participants' experience of diabetes and clinical consultations; raising concerns with health professionals in

primary and secondary care; participants' experience of either usual care or the intervention; and trial participation.

For the semi-structured interviews, participants in both trial arms will be purposefully sampled to include those with Type 1 or Type 2 diabetes, new and existing patients, and people with different ages/genders/socio-economic backgrounds, and where possible different co-morbidities, following a maximum variation sampling strategy [49]. It is necessary to include interviews with participants in the usual care arm of the trial to explore how patients normally voice their agendas during diabetes consultations, and with what consequences. The interviews will take place a short time after the final follow up at six months, to avoid any influence of the interview on these measures. Interviews will be conducted at a location that is convenient for the participant.

A topic guide will be used, which has been developed with involvement from the PPI co-applicants, to ensure that the primary issues are covered, whilst allowing flexibility for new issues to emerge from each interview. Interviews will be digitally recorded, fully transcribed and anonymised to protect confidentiality.

In addition to the interviews with participants, approximately ten interviews with health professionals (e.g. health care assistants, research nurses, and diabetologists) involved in the study at each research site will be conducted near the end of the trial. They will explore professionals' views about the intervention and issues around implementation. A flexible topic guide will be employed and these interviews will explore: professionals' experience of diabetes and clinical consultations; addressing patients' concerns in secondary care; professionals' experience of usual care and the intervention; and trial participation.

The audio-recordings from both the consultations and interviews will be transcribed and read in detail by team members who are experienced in qualitative research methods and a list of common themes and concepts drawn up [50]. Data collection and analysis will be iterative and on-going, with the coding frame refined as new themes and categories are identified from subsequent interviews [51]. The qualitative data will be managed using Nvivo software.

Cost-effectiveness methods

An economic evaluation will not be conducted as part of this pilot study. However, data will be collected to inform the design of the economic evaluation alongside the planned definitive trial, by: comprehensively estimating the range of care resource use and cost impacts related to the intervention (i.e., potential costs of implementation using HCA or research nurses or DSNs or other modes of delivery) and its expected outcomes; refining and justifying the choices of outcome measures for health-related quality of life; and testing the practicality and validity of methods for collecting patient-reported resource/service use; and providing some preliminary estimates of different parameters and their variances.

Ethics and dissemination

The study was approved by the NHS Research Ethics Committee North West – Preston (13/NW/0123).

Dissemination of the results and projected outputs will be appropriate to that of a pilot study, and the key output will be an application to an appropriate funder for a definitive trial of the intervention. As the research question was generated via the Patient and Public Involvement Group, and service users are integral to the research team, the results of the study will be of particular interest to those who use diabetic services. The PPI co-applicants with other members of the research team will disseminate the results of this pilot to the trial participants, via two workshops, which will be conducted at neutral locations towards the end of the study.

The results from the pilot will be more widely disseminated in order to share our experiences and to generate enthusiasm for the future definitive trial. We will inform people with diabetes through articles in lay health magazines, electronic forums and presentations. We will inform clinicians and health service managers through submissions to appropriate journals and presentations at suitable conferences.

Results from the future definitive trial would be disseminated widely through a variety of media, including peer-reviewed journal articles and conference presentations, with an emphasis on reaching NHS policy makers and commissioners, health professionals and service users.

DISCUSSION

During the development phase of the research, three key methodological aspects were discussed.

The research team has purposely chosen to trial the PACE-D (intervention) in secondary care – a decision which was much debated during the study development phase. Discussions included people with diabetes (both Type 1 and Type 2, including those who have experience of consultations with diabetologists in the hospital outpatient setting), general practitioners, diabetologists, diabetes specialist nurses, practice nurses, and lay and professional members of the Diabetes Research Network and Primary Care Network. Following these lengthy discussions, a decision was made to sample new and existing patients attending clinic appointments with six diabetologists at two different hospitals, as it is believed that these people may have a particular set of concerns. If the intervention is successful in this population, we may consider undertaking future research with the intervention in primary care settings, where patients may have a different set of concerns.

The potential for contamination between the trial arms resulting from the use of individual patient randomisation was debated by the research team, and a number of alternative randomisation strategies were considered, including cluster randomisation of clinics, consultants or sites. The research team reached a consensus that contamination is unlikely in this context given that the active ingredient of the intervention is use of the PACE-D tool, and therefore decided to use individual randomisation.

People with diabetes identified the research topic and requested that the intervention (PACE-D) should be facilitated by a DSN. However, while the study was being designed and discussions with local NHS partners were undertaken, it was apparent that DSNs are increasingly time pressured. A pragmatic decision was therefore made by the research team, including lay representatives, that the trial intervention should be facilitated by a number of HCAs routinely present at general outpatient diabetes clinics, and who will be trained in study procedures by a DSN co-applicant. It is thought that this will provide a valid insight into how the intervention would work in both a future trial and the 'real world' clinical setting.

CONCLUSION

People with diabetes need to actively monitor and manage their condition; however, they are not always able to discuss things which concern them at clinical consultations with their diabetologist. Guidelines in the UK emphasise the importance of more actively involving people with diabetes in the consultation process and on-going management of their condition. The DIAT study aims to inform best practice in this area, by evaluating an intervention to assist patients to produce an agenda for their consultation. We think that this may enable patients to play a more active role in that consultation and subsequently make them more enabled, and hence successful at managing their condition.

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Figure 1: DIAT trial schedule

Study procedure	Screening	Pre-clinic attendance	Clinic attendance (pre-consultation)	3 month follow up	6 month follow up
Identification of potential participants on clinic lists for relevant consultants	x				
Letter of invitation and Participant Information Sheet sent to potential participant	x				
Phone call to potential participant to ascertain interest	x				
Postal Consent Form sent to interested participant	x				
Follow-up phone call to non-responders (to clarify whether patient intends to consent)	x				
Randomise on receipt of Consent Form at PenCTU		x			
Send Questionnaire Booklet (baseline) on receipt of Consent Form at PenCTU		x			
PACE-D intervention			x		
Questionnaire Booklet: • Current medications • Experience of participating in DIAT (treatment arm only at 6 months only) • Audit of Diabetes-Dependent Quality of Life • Client Services Receipt Inventory • Diabetes Empowerment Scale • Diabetes Self-Care Activity Questionnaire • Diabetes Treatment Satisfaction Questionnaire ('status' and 'change' versions) • EuroQol-5L • Patient Enablement Instrument • Patient Report of Communication			x	x	x
Retrospective check of medical notes: • Demographics (e.g. BMI) • HbA1c results • Medication use (in 10% of participants) • Healthcare service use data collection (in 10% of participants) • Adverse events (in 10% of participants)			x	x	x
Qualitative interview (Post-clinic visit with purposive sample)				x	

90x127mm (300 x 300 DPI)