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## Overall experiences of people with New Onset Type 1 Diabetes involved in a physical activity study

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Trial experience of newly diagnosed patients with Type 1 Diabetes

**Overall experiences of people with New Onset Type 1 Diabetes involved in a physical activity study**

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Trial experience of newly diagnosed patients with Type 1 Diabetes

## **ABSTRACT**

**Objectives:** Regular physical exercise may preserve beta cell function in newly diagnosed adults with Type 1 diabetes (T1D). However clinical trials to test this theory require the recruitment and retention of adults with new onset T1D, which can be challenging. We sought to determine the overall experiences of newly-diagnosed adults with T1D in an exercise study with the aim of understanding issues that influence the retention of trial participants in such studies.

**Design:** Qualitative methodology using individual face to face (n=6) and telephone interviews (n=14). Interview transcripts were thematically analysed using the Framework Method

**Setting:** The study took place at five participating UK hospitals.

**Participants:** Twenty participants in the Exercise for Type 1 Diabetes (EXTOD) study were interviewed to explore their study experiences and identify motivators and deterrents towards the study. Participants in control and intervention arms were interviewed, as were patients who had completed (n=16) and withdrawn (n=4) from the trial.

**Results:** Participants revealed barriers and facilitators to retention; the majority were generalisable to clinical trials of people with newly-diagnosed T1D. Lack of time, work pressures, level of health professional support, volume, clarity and consistency of information and feedback and a desire for knowledge about their condition were all cited as influencing factors to trial retention.

Trial experience of newly diagnosed patients with Type 1 Diabetes

**Conclusions:** To our knowledge, this is the first qualitative study to examine the experience of being involved in an exercise trial by people with T1D . Findings suggest: appointments could be shorter, available outside of standard working hours and planned longer in advance; study information should be clear, consistent and offered in electronic and paper formats; questionnaires need keeping to a minimum; healthcare support and feedback needs providing regularly; thought is required around how to support participants in the non-exercising arm. These considerations may improve participant retention rates in new onset T1D studies.

**Keywords:** Type 1 diabetes; Exercise; Physical Activity; Trial Retention; Clinical Trials; Participants

#### **Strengths and limitations of this study**

- A qualitative, interview study was undertaken to explore, in-depth, the experiences of people with type 1 diabetes who were participating in an exercise study.
- The study was multi-site, taking place at five participating hospital trusts across the UK.
- Rigorous data collection and analysis techniques were undertaken, using the Framework approach.
- Participants were purposively sampled to allow for variation in the sample characteristics.
- To our knowledge, this is the first qualitative study to examine people with T1D experiences of being involved in an exercise trial.

Trial experience of newly diagnosed patients with Type 1 Diabetes

## INTRODUCTION

Type 1 diabetes (T1D) is a chronic autoimmune condition characterised by immune mediated destruction of insulin producing pancreatic beta cells<sup>1</sup>. Significant numbers of  $\beta$  cells are present at the time of diagnosis<sup>2</sup>, but this continues to decline following diagnosis. Preservation of  $\beta$ -cell function is associated with improved glucose control, reduced risk of retinopathy and nephropathy and reduction in rates of hypoglycaemia of more than 50%<sup>3</sup>. Interventions that can preserve residual  $\beta$ -cell function in new-onset T1D are needed. Furthermore, therapies proven to preserve  $\beta$ -cell function in new-onset T1D can be taken forward into trials of T1D prevention.

In animal models of Type 1 and Type 2 diabetes (T2D), healthy humans, and in people with impaired glucose tolerance with T2D, regular exercise has been shown to preserve  $\beta$ -cell function<sup>4</sup>. For example, in people at risk of T2D, one hour of walking three times a week for eight months improved  $\beta$ -cell function by 60%<sup>5</sup>. These findings have not been tested in people with T1D and there is thus a need for a prospective clinical trial to test the hypothesis that exercise preserves  $\beta$ -cell function in people newly diagnosed with T1D.

The incidence rate of T1D is low, with 1 in 1000 affected and recruitment of people with T1D to clinical trials is challenging<sup>6-8</sup>, with studies showing recruitment rates as low as 17%<sup>6</sup>. This means that retaining newly diagnosed patients with T1D who are recruited to studies is even more important. In studies of immunotherapeutic agents for T1D, drop out rates are 12-14%<sup>9 10</sup>; however higher rates have been reported for exercise studies. In a meta-analysis of unsupervised exercise programmes, 20% of studies had a dropout of > 20%, 32% a dropout of 10–20%, and 48% a dropout of < 10%<sup>11</sup>.

Barriers to participation in clinical trials are well documented<sup>12</sup>, although no studies have looked at barriers to recruitment in patients with newly diagnosed T1D. There are very few studies that have

## Trial experience of newly diagnosed patients with Type 1 Diabetes

1  
2  
3 looked at how to improve retention rates of patients in a clinical randomized controlled trial (RCT).  
4  
5 Those studies that have been done have concentrated on strategies to improve retention rather than  
6  
7 barriers to retention<sup>13</sup>. No studies have looked at barriers to retention in patients newly diagnosed  
8  
9 with T1D. We wished to address this important deficit by qualitatively exploring the experiences of  
10  
11 people with newly diagnosed T1D who participated in the a recently completed exercise and T1DM  
12  
13 study<sup>14</sup>.  
14  
15

## 18 **METHODS**

### 21 **Setting, access and recruitment**

24 Study participants were from the EXTOD study, whose protocol has been described previously [13].  
25  
26 In brief, all patients aged between 16 and 60 years, diagnosed with T1D in the previous three months,  
27  
28 from 19 UK hospital sites, were invited to participate. EXTOD had two phases. Phase 1 consisted of a  
29  
30 qualitative study to determine attitudes and barriers to exercise in patients with newly diagnosed  
31  
32 T1D. Phase 2 was a pilot RCT to assess uptake, intervention adherence, drop-out rates, and rate of  
33  
34 uptake in the usual care group during a 12 month exercise intervention (where the participants came  
35  
36 from for this study).  
37  
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40

41 At the time of recruitment to the pilot RCT (phase 2) study, all patients received participant  
42  
43 information leaflets and provided informed consent to potentially take part in a interview to explore  
44  
45 their experience of being involved in the pilot RCT. Twenty participants from five participating sites  
46  
47 (Birmingham, Leeds, Bristol, Gloucester, Taunton) were later selected using purposive sampling to  
48  
49 ensure variety in terms of their key study characteristics<sup>15</sup>. Participants were sampled in relation to  
50  
51 their age, gender, study arm (intervention/control) and study status (completed/withdrawn). Selected  
52  
53 participants were sent a letter at the end of the pilot RCT, informing them that they would be  
54  
55 contacted by the EXTOD team. This was followed, a week later, by a phone-call from a member of  
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## Trial experience of newly diagnosed patients with Type 1 Diabetes

1  
2  
3 the EXTOD team (nurse or doctor) to check they were happy to be interviewed. If willing, they were  
4  
5 then telephoned by the researcher (CH), who has a nursing background and is an experienced  
6  
7 qualitative researcher (though she had not previously undertaken any research in this area), to arrange  
8  
9 a suitable time and date for her to undertake the interview. CH had had no contact with participants  
10  
11 prior to this and participants were unaware of the researcher's background. All participants agreed to  
12  
13 be interviewed.  
14  
15

16  
17  
18 This study had ethical approvals from The West Midlands and Solihull Research Ethics Committee  
19  
20 (10/H1206/4).  
21  
22  
23  
24  
25

### **Patient Involvement**

26  
27  
28 The research question was derived from T1D patients attending clinic asking clinicians about any  
29  
30 benefits and barriers to exercise, as they were aware that much work had been undertaken on this  
31  
32 topic in T2D patients, but not in T1D patients. This led to the formulation of the research question and  
33  
34 an application for funding to undertake this research. Patients were involved in the study design from  
35  
36 the outset, as the researchers presented the study proposal to them, and asked for any comments  
37  
38 relating to it. Issues relating to the conduct of the study, such as the potential burden of the exercise  
39  
40 intervention to participants, were also discussed and any feedback was incorporated into the study  
41  
42 design. Patients also contributed to the study conduct by sitting on the study management committee  
43  
44 and helped with study oversight, including helping to develop approaches to improve study  
45  
46 recruitment. Study findings were fed back to participants through an informal feedback evening where  
47  
48 the findings were presented. In addition, a summary of findings was posted to participants.  
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## Trial experience of newly diagnosed patients with Type 1 Diabetes

**Data collection**

Participants at the hospital where the researcher was based (Birmingham) were given the option of being interviewed face-to-face at the hospital, or by telephone. The remaining participants were all interviewed by telephone, due to financial, time and travel constraints. All interviews were carried out with only the participant and CH present.

Interviews were carried out by CH, using a semi-structured topic guide (Table 1) that was developed in consultation with the EXTOD researchers. The interviews lasted between 20 to 50 minutes. No repeat interviews were conducted. Areas for discussion included levels of health professional support, information provided about diet and exercise and issues relating to recruitment and follow up. All interviews were digitally recorded and transcribed verbatim by a local transcription company.

**Table 1: Topic Guide for Interview Study**

<b>Openers</b>	If I could start by asking you how long ago you took part in the study? How did you find the experience?
<b>Diet and Exercise Information</b>	How appropriate was the advice about diet and exercise in relation to its content and volume? Do you feel being recruited to the study so soon after diagnosis was a good thing or would you have preferred more time? When would have been an appropriate time? How well were able to take in the information you were given? Would it have been helpful to see the dietician again, or do you feel that once was enough? Did you refer to the study information booklet? If so, how helpful was the information booklet? Which sections of the booklet particularly helpful or unhelpful? Do you use the booklet as a reference guide now? Did any aspects of your diet change following looking at the information booklet? Can you think of any better ways in which the information could have been delivered?
<b>Health Professional Support</b>	How well supported did you feel in terms of the clinical support you received? Did you feel you more or less well supported through being on the trial? Do you feel being in the trial was better or worse in terms of the number of doctors/nurses you saw? Why? Were you happy seeing the same nurse all the way through the trial or would you have preferred more

## Trial experience of newly diagnosed patients with Type 1 Diabetes

	<p>variety? Did you mind no longer seeing the nurse you saw when you were diagnosed?</p> <p>Do you mind not seeing these study doctors/nurses on a regular basis now?</p> <p>How well balanced were the follow up visits in terms of the health professional you saw? Would you have preferred more/less visits with a doctor/nurse etc...Or do you feel it was the right amount of time with each?</p> <p>Overall, how well supported by the doctors and nurses did you feel?</p>
<b>Recruitment and Follow Up</b>	<p>Where did you first hear about the trial from? Who approached you?</p> <p>What appealed to you about taking part in the study in the first place? What were your reasons?</p> <p>Was there anything that put you off taking part in the study?</p> <p>How easy to complete and understand were the questionnaires you received?</p> <p>During the trial you were required to have extra blood tests. How did you feel about having the extra bloods?</p> <p>How much did you feel the follow up visits were focused on you and how much did you feel they were focused on the trial and form filling etc...Was this appropriate or could it be weighted differently?</p> <p>Would you have preferred most of the follow up visits to have taken place face to face or over the phone?</p> <p>Can you describe whether being on the study affected your confidence levels in terms of undertaking exercise?</p> <p>What were your reasons for leaving the study?</p> <p>Why did you choose to continue/discontinue with the 5year FU as part of the study?</p>
<b>Motivational Interviewing (intervention group only)</b>	<p>How useful do you feel the extra support you were given by the nurse about managing your diabetes and exercising was? What were the pros and cons of talking to the nurse about this?</p> <p>Would it have been helpful to have weekly phone calls from the nurse to check on how you were getting on?</p> <p>Did the amount of exercise you undertook change as a result of these talks with the nurse or did it stay the same?</p> <p>Did the type of exercise you undertook change or stay the same following a) diagnosis and b) the intervention?</p> <p>How much physical activity were you carrying out before your diagnosis compared to a) during the study and b) now? Has your exercise levels been maintained post-study?</p> <p>Did you feel more or less confident about carrying out exercise following the intervention with the nurse?</p> <p>What more could have been done to encourage you to exercise?</p> <p>What sort of approach might have worked for you to help you to exercise?</p> <p>Some participants did not make their exercise target. Can you think how we could help them reach this target?</p> <p>What methods did you use to increase your exercise levels?</p>
<b>Future Development of Study</b>	<p>If there was one thing we could do to make the study easier for you to take part in what would it be?</p> <p>We are planning to undertake a larger scale study similar to the one you have taken part in. What sort of things would you change about the study that might make people want to take part in it more?</p> <p>Overall, what did you feel was good or bad about taking part in the study?</p>

## Trial experience of newly diagnosed patients with Type 1 Diabetes

	Do you think you would be more or less likely to participate in clinical trials following this experience?
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**Data Analysis**

Data analysis was carried out during the interview period to enable the interview process to be shaped by the emerging data themes and to identify when saturation had been reached. An inductive approach to data analysis was taken and themes were derived from the interview dataset. Data was coded by CH and was inserted into a framework analysis matrix Excel spreadsheet, to enable data ordering and synthesis, whilst retaining the meaning and feeling of the interviewees' words<sup>16</sup>. Themes were developed independently by reading and rereading the transcripts and through discussion with research team members (CH, PN and SG). The interviews were then analysed using thematic analysis<sup>17</sup>. Transcripts were not returned to participants to comment on during this process.

**RESULTS****Participants**

Twenty participants were interviewed; six face to face and fourteen by telephone (Table 2). Participants were recruited from all five participating sites; eleven were male, ages ranged from 19-55 and all were of white British ethnic origin. Thirteen had been allocated to the intervention group and seven to the usual care comparator. Sixteen participants had completed EXTOD, whilst four had withdrawn for reasons including work commitments, a cancer diagnosis, and difficulties accepting their diabetes diagnosis.

## Trial experience of newly diagnosed patients with Type 1 Diabetes

**Table 2: Characteristics of participants**

Participant	Gender	Centre	Treatment arm	Complete/with drew	Interview format
1	Female	Birmingham	Intervention	Completed	Telephone
2	Male	Birmingham	Control	Completed	Face to face
3	Male	Birmingham	Intervention	Completed	Face to face
4	Female	Birmingham	Intervention	Withdrew	Telephone
5	Male	Leeds	Intervention	Withdrew	Telephone
6	Female	Leeds	Control	Withdrew	Telephone
7	Female	Birmingham	Intervention	Completed	Face to face
8	Female	Birmingham	Intervention	Completed	Face to face
9	Male	Birmingham	Control	Completed	Face to face
10	Male	Birmingham	Control	Completed	Telephone
11	Male	Birmingham	Intervention	Completed	Telephone
12	Male	Taunton	Intervention	Completed	Telephone
13	Male	Gloucester	Control	Completed	Telephone
14	Female	Bristol	Intervention	Completed	Telephone
15	Male	Bristol	Control	Completed	Telephone
16	Male	Bristol	Intervention	Completed	Telephone
17	Male	Bristol	Control	Withdrew	Telephone
18	Female	Leeds	Intervention	Completed	Telephone
19	Female	Birmingham	Intervention	Completed	Face to face
20	Female	Taunton	Intervention	Completed	Telephone

## Trial experience of newly diagnosed patients with Type 1 Diabetes

**Themes**

The interviews yielded data on five main themes and these help formulate the barriers and facilitators to trial participation (Table 3). These themes were: study paperwork; feedback; barriers to continued participation; coming to terms with diagnosis of T1D; effect of allocated arm.

**Table 3: Facilitators and barriers to continued Clinical Trial Participation in People with Type 1****Diabetes Mellitus**

<b>Facilitators</b>
<ul style="list-style-type: none"> <li>• Consistency and continuity of health professional support</li> <li>• Clear, detailed and relevant information about diabetes and its management</li> <li>• Availability of both paper and electronic information and documentation</li> <li>• Reduction in volume of study documentation</li> <li>• Flexible access to trial facilities outside of normal working hours</li> <li>• Appointments scheduled in advance to allow for planning around work and social lives</li> <li>• Early feedback of trial findings</li> </ul>
<b>Barriers</b>
<ul style="list-style-type: none"> <li>• Time</li> <li>• Work pressure</li> <li>• Travelling to appointment</li> <li>• Length of visits</li> <li>• Length of study</li> <li>• Coming to terms with diagnosis</li> <li>• Being able to maintain exercise levels</li> <li>• Being allocated to the control (non exercising arm)</li> </ul>

**Study Paperwork**

Two main subthemes emerged within the 'study paperwork' theme; these were study information and study questionnaires.

## Trial experience of newly diagnosed patients with Type 1 Diabetes

*Study information*

The volume, clarity and consistency of information provided were important in determining how well informed participants' felt about their diabetes and its management. Though a few participants felt they were given too much information, most felt that although there was a lot of information, it was useful, relevant and necessary so soon after diagnosis. Generally the information was cited as interesting, manageable and straightforward. Others spoke of how they valued the repetition of some information, as it meant they could fully absorb it.

*'To be honest I thought it was perfect...I was sort of drip-fed information throughout the year really, and it was very good...After...The shock of being told you're Type 1 diabetic...I found it very good and the team was extremely helpful.'* EXTOD 12

Most participants were happy receiving paper information, finding it easy to read and acknowledging that not everyone had Internet access. Others, especially younger participants, stated they would have preferred digital information, such as Apps, to access information faster. One participant suggested having a centralised webpage specific to the hospital's diabetes unit, with links to different diabetes resources on it. Participants supplemented the trial information with other resources, such as the 'Carbs and Cal' book<sup>18</sup>. Others used digital resources, such as the 'Carbs and Cal' or 'Fitness Pal' apps and online information<sup>18</sup>.

*'Being a bit of a technology geek, I went with the app which is the Carbs and Cals app...It will give you a particular breakfast, like Alpen...and then it will show you...the size of portion that you're supposed to have, and how much insulin you're supposed to take.'* EXTOD 2

*Study questionnaires*

Most participants felt the study paperwork was too long and time-consuming, 'switching off' from it as a result, as it got in the way of work and personal lives. Much paperwork was questionnaires

## Trial experience of newly diagnosed patients with Type 1 Diabetes

1  
2  
3 relating to diet, exercise and quality of life that were completed at the study visit. Participants felt that  
4  
5 although the paperwork was generally easy to complete and understand, it could also be repetitive,  
6  
7 confusing and contradictory, containing irrelevant, non-specific questions, which were hard to relate  
8  
9 and respond to.

10  
11 *'I remember always getting given the questionnaire sheet when I was having my bloods done. And I*  
12 *could just never fill it in. It used to be like – I used to say to my dad can you ask my questions and*  
13 *then I could do it, but it did go on for quite a while... And it was the same the second time I did it as*  
14 *well, and I was like I don't know what to put for these questions again. It seemed like I was doing the*  
15 *same thing.'* EXTOD 19  
16  
17  
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#### 24 Feedback

25  
26  
27 Some participants voiced disappointment at receiving little trial feedback, stating that the opportunity  
28  
29 for feedback had incentivised them to join the trial, as a way of finding out about their diabetes and  
30  
31 also that they wanted to learn more about the long term trial outcomes.  
32

33  
34 *'It would be good to have some follow-up information...I wasn't quite sure how my fitness level was*  
35 *affected...And I never got to find out if it actually improved.'* EXTOD 1  
36  
37  
38  
39  
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#### 41 Barriers to continued participation

42  
43  
44 Seventeen of the 58 participants who were randomised into the original EXTOD study withdrew  
45  
46 before the end of the study. We thus sought to understand why this might have happened.  
47  
48  
49  
50

51  
52 Participants described practical barriers as the most likely reasons for dropping out. These included  
53  
54 time and work pressures, dislike of blood tests, travelling to appointments, the long study duration,  
55  
56 volume of visits and moving away.  
57

## Trial experience of newly diagnosed patients with Type 1 Diabetes

1  
2  
3 *'I'm not bothered for taking blood or doing injections or anything like that...But I can remember*  
4 *feeling bothered by that at the time. I think because I was very ill, really, still, and still quite fragile*  
5 *... I can remember that upsetting me...Because it was a study and because I didn't have to do it...If*  
6 *you volunteered to have a blood test and it takes a few times for them to take the blood, it's kind of*  
7 *like putting yourself through something difficult that you didn't really need to do.'* EXTOD 6  
8  
9  
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14  
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16 The long study duration also deterred many participants, who felt it was too long to fully commit to,  
17 meaning they became less vigilant at attending appointments or completing study documentation due  
18 to the repetition involved.  
19

20  
21 *'It's quite long. I think that was quite daunting. It turned out to not really be an issue, but because*  
22 *it's something that I could kind of blend into my lifestyle quite a lot. Because I suppose it didn't really*  
23 *require any prolonged visits to the clinic or anything because it was mostly just things that I could do*  
24 *myself. But initially that was a bit daunting because it's a year.'* EXTOD 16  
25  
26  
27  
28  
29  
30

31 For most, committing to the EXTOD study had proved difficult, due to the time it required off work.  
32 This led to difficulties for participants in ensuring they could always attend appointments and  
33 sometimes proved costly, due to having to take unpaid leave for study visits.  
34  
35

36  
37 *"The time that you're having to have off work...Often it's unpaid leave so obviously that can be quite*  
38 *difficult."* EXTOD 18  
39  
40  
41  
42

43 These time pressures had led to two of the interviewed participants withdrawing from EXTOD prior  
44 to completion. Solutions to these problems suggested by participants -who had both withdrawn and  
45 remained in the study - included offering more flexible appointment times and planning clinic visits  
46 further in advance so there was more time to plan around them.  
47  
48  
49

50  
51 *'I left...Because I didn't have enough time...The study is of such a long duration and I just found that*  
52 *too challenging with work...If you had appointments at eight o'clock in the evening every time you*  
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## Trial experience of newly diagnosed patients with Type 1 Diabetes

1  
2  
3 *needed me then so be it...I have to do a hell of a lot of juggling in order to fit that sort of stuff in.'*

4  
5 *EXTOD 17*

6  
7  
8  
9 Coming to terms with diagnosis of T1D

10  
11 Some participants spoke of how they had struggled to come to terms with their T1D diagnosis, with  
12  
13 one participant citing this as their reason for withdrawing from EXTOD. For this participant, her  
14  
15 difficulties coping emotionally with her diagnosis had prompted her doctors to advise her to  
16  
17 withdraw.

18  
19 *"Don't think it kind of really sank in as to what I'd been diagnosed with... It had kind of hit me and I*  
20  
21 *wasn't really dealing with having it...I wasn't taking my insulin and checking my levels as much...The*  
22  
23 *doctors...Felt that it was best that I was taken off it."* EXTOD 4

24  
25  
26  
27 Effect of allocated arm

28  
29 Some participants, who had been allocated the exercise intervention, spoke of difficulties maintaining  
30  
31 the level of exercise expected of them, due to lack of motivation or the extra time it took.

32  
33 *'I think a year in it seemed to get a little bit "Oh God I've been doing this for a year now"...A year's*  
34  
35 *a long time... Because towards the end as well, it was like you had to come in and then I had to do the*  
36  
37 *gym thing, and it was kind of like... "oh this is getting really laborious".'* EXTOD 2

38  
39  
40  
41 Others, in the usual care comparator group, spoke of how this disincentivised them from remaining in  
42  
43 EXTOD as they were not receiving the exercise benefits they had hoped for.

44  
45 *"The sort of people that...Take part...Are often similar to me in kind of quite wanting to do the*  
46  
47 *exercise, and presumably about half of the time you get randomised into not doing the exercise. And I*  
48  
49 *don't know whether that's off-putting as well."* EXTOD 16

Trial experience of newly diagnosed patients with Type 1 Diabetes

## **DISCUSSION**

This is the first study to examine the experiences of people with T1D taking part in an exercise intervention trial. The findings have highlighted issues that should be considered when designing clinical trials involving this population group. Clinical trials which reflect the needs, wants and preferences of participants can lead to improvements in retention rates, statistical power and, in the longer term, to studies with more credible findings. The findings suggest that timing is an important consideration for many participants. Many may be offered trial entry shortly after their condition's onset and may be experiencing multiple health and lifestyle changes. This highlights the need for sensitive communication of information from health professionals when introducing clinical trials. The disappointment of some participants at being allocated the usual care group also highlights the need for a clear explanation of equipoise and other clinical trials terminology, so participants can make informed treatment decisions, minimising the potential for withdrawal rates after randomisation<sup>19</sup>. Additional measures that could help with this are offering the intervention at the end of the study or randomising more to the exercise arm than the control arm, to enable more participants access to the intervention.

The study has illustrated the need for the transmission of clear, relevant and useful information to clinical trial participants. Participants showed preferences for a wide-range of delivery modes, including paper formats, websites, apps and Internet forums. The use of appropriate, accessible media to convey information effectively and engage with participants is dependent on individual preferences and may be influenced by factors such as age, gender and income<sup>20</sup>. The popularity of Apps and multimedia technologies amongst participants indicates that these modes of information delivery should be incorporated specifically into trials with T1D participants, who are likely to be a younger, more technologically minded population group than trials with T2D participants. Future trial designs could offer paper and electronic information so participants' can utilise their preferred resource. Similarly, when collecting data, a range of methods could be employed, including paper documentation, spreadsheets, phone apps, emails and websites. Demonstrating versatility and

## Trial experience of newly diagnosed patients with Type 1 Diabetes

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2  
3 flexibility in data collection techniques may help motivate participants to complete study  
4  
5 documentation that they might otherwise omit. The importance of providing regular study feedback to  
6  
7 participants should also be considered, through letters, emails and presentations, so that their  
8  
9 contribution is acknowledged and valued <sup>21</sup>.

10  
11  
12  
13 Finally, the interview findings highlighted that practicalities such as work pressures, time  
14  
15 commitments and geographical location influenced participants' ability to commit to the trial. T1D  
16  
17 onset usually occurs at a young age, with most people being diagnosed before 35 <sup>22</sup>. As a result,  
18  
19 people with T1D are likely to have busy lives incorporating work, family and social engagements,  
20  
21 making committing to a clinical trial difficult. This is verified by the commonest reason cited for the  
22  
23 high dropout rate (29%) from EXTOD being time and work commitments. To rectify this, more  
24  
25 flexible study visit times could be offered, with the option of attending outside normal working hours,  
26  
27 such as evenings and weekends. Additionally, the provision of a timetable of scheduled appointments  
28  
29 at the study outset would allow participants to plan for them. Improved hospital transport links could  
30  
31 also facilitate ease of study attendance <sup>23</sup>. By incorporating a flexible approach to these practical  
32  
33 barriers, participants will experience less difficulty in complying with study visits, improving  
34  
35 retention rates. Consideration should also ensure that the exercise intervention can be integrated into  
36  
37 people's lifestyles, without adding to their pressurised schedules. This could be done by providing a  
38  
39 range of exercise options, in a range of locations and within a realistic timeframe, to minimise the  
40  
41 likelihood of participants becoming over-faced by the extra commitment they have taken on.

42  
43  
44  
45 Many of the challenges to clinical trial retention in people with T1D are similar to the challenges  
46  
47 facing the general population who are recruited to clinical trials <sup>24-28</sup>. The issues and challenges  
48  
49 participants faced, such as the long study duration, difficulties completing documentation and time  
50  
51 pressures, are also likely to be challenges for the general clinical trials population, including T2D.  
52  
53 However, this study has identified that although many of these trial related issues are not specific to  
54  
55 T1D populations, the reasons for these issues are likely to be different. For example, people with T1D  
56  
57  
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59  
60

## Trial experience of newly diagnosed patients with Type 1 Diabetes

1  
2  
3 or T2D may report that time pressures prevent them from committing to a clinical trial. However,  
4  
5 whilst for the T1D participant, time pressures may stem from work priorities, the T2D participant time  
6  
7 pressures may stem from regularly caring for grandchildren. By understanding more about the reasons  
8  
9 behind these barriers to trial recruitment and retention, trials can be designed to accommodate and  
10  
11 facilitate the wants and needs of these different groups. The average age of participants entering  
12  
13 clinical trials is over 50 years of age<sup>26 29</sup>. This contrasts with the randomised EXTOD participants,  
14  
15 whose mean age was 32 years. This younger age-group is likely to face more difficulties in adhering  
16  
17 to rigid time schedules and appointments due to added work, family and social pressures. This is  
18  
19 important for clinicians and researchers to acknowledge, allowing them to design T1D studies that  
20  
21 will facilitate trial recruitment and retention, by offering more flexible appointment times, out-of-  
22  
23 hours services and realistic, manageable exercise schedules. These practical solutions are important  
24  
25 considerations for retaining participants in clinical trials and must be valued if rich and full trial  
26  
27 datasets are to be obtained. When considering study design, thought must be given to how to increase  
28  
29 recruitment, as well as how to make the study experience appealing to participants once they have  
30  
31 consented. By paying attention to the participant's perspective, the chances of retaining participants  
32  
33 for the study duration will increase, improving trial outcomes and participant satisfaction with trial  
34  
35 entry.

### **Strengths and limitations**

36  
37  
38  
39  
40 The interview participants were selected from five UK hospitals, increasing the transferability of the  
41  
42 findings to a range of settings. Participants were purposively sampled, stratifying them according to  
43  
44 age, gender, randomisation arm and whether they had completed or withdrawn from the study. This  
45  
46 enabled a diverse and comprehensive collection of narratives to be gathered and analysed, enhancing  
47  
48 the trustworthiness of the findings. However, although 12% of EXTOD participants recruited were  
49  
50 non-White, none of the participants recruited to the qualitative study were non-White. This lack of  
51  
52 representation is due to our exclusion of ethnicity as a criterion in our purposive sampling. Although,  
53  
54 we did not purposefully exclude non-White participants from the sample, the likely reason for their  
55  
56  
57  
58  
59  
60

## Trial experience of newly diagnosed patients with Type 1 Diabetes

1  
2  
3 lack of inclusion is because T1D is far more common in White populations than other ethnic groups  
4  
5 <sup>30</sup>. Additionally, many of the geographical locations we recruited from had a White population of over  
6  
7 84% <sup>31-33</sup>. Despite this, including ethnicity in our purposeful sample could have ensured that non-  
8  
9 White populations were represented. In addition, due to the interview participants being situated  
10  
11 around the UK, most interviews were conducted by telephone. However, where possible, participants  
12  
13 were given the choice of being interviewed face-to-face or by telephone, allowing them to choose the  
14  
15 setting they found most relaxing, thus increasing opportunity for open dialogue between interviewees  
16  
17 and researcher. The fairly even split between participants choosing face-to-face and telephone  
18  
19 interviews suggests that providing a choice of setting may increase recruitment and retention to trials,  
20  
21 giving participants the opportunity to select their most comfortable environment.  
22  
23  
24

**CONCLUSION**

25  
26 To our knowledge, this is the first qualitative study to examine T1D participants' experiences of being  
27  
28 involved in a clinical trial. Although people may be initially motivated to enter clinical trials for  
29  
30 reasons such as altruism and a desire for information, practical factors such as work and time  
31  
32 constraints, study duration and financial difficulties often act as deterrents for remaining on trials.  
33  
34 Though these issues in themselves are not unique to the T1D population, the *reasons* for these issues  
35  
36 are likely to be different. These reasons need considering when designing T1D clinical trials, to  
37  
38 ensure that appropriate modifications are built into the trial design to enable people with T1D to  
39  
40 participate with minimal disruption to their lives.  
41  
42  
43  
44

45 The study findings have highlighted that differences do exist between T1D participants and the  
46  
47 general clinical trials population. Firstly, the younger age of people with T1D at recruitment may  
48  
49 make it harder for them to commit to clinical trials due to increased work, family and social pressures;  
50  
51 this was verified by study participants. Secondly, the study has indicated that using multimedia  
52  
53 technology might benefit T1D participants, who are used to handling information electronically. It has  
54  
55 highlighted that to increase retention to T1D trials, improvements to trial design are required. This can  
56  
57  
58  
59  
60

Trial experience of newly diagnosed patients with Type 1 Diabetes

be done through providing flexible access to services, clear and relevant study information, documentation and feedback, as well as consistent healthcare support.

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### **COMPETING INTERESTS STATEMENT**

None declared.

Trial experience of newly diagnosed patients with Type 1 Diabetes

### **REPORTING GUIDELINES**

The COREQ reporting guidelines were followed.

### **DATA SHARING STATEMENT**

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

### **AUTHOR CONTRIBUTIONS**

All authors (CH, PN, RA, AD, KS, AK, SG) contributed substantially to conception and design, or acquisition of data, or analysis and interpretation of data. All authors drafted or revised the article critically for important intellectual content. All authors gave final approval of the version to be published.

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Table 1: COREQ Checklist for manuscript ID bmjopen-2018-022353

Checklist number	Item	Description	Location in manuscript (page number)
1	Interviewer/facilitator	Which author conducted interview/focus group	Page 6
2	Credentials	What were the researcher's credentials	Page 1
3	Occupation	What was their occupation at the time of the study	Page 6
4	Gender	Was the researcher male or female	Page 6
5	Training	What experience or training did the researcher have	Page 1, page 6
6	Relationship established	Was a relationship established prior to study commencement	Page 6
7	Participant knowledge of researcher	What did participants know about the researcher	Page 6
8	Interviewer characteristics	What characteristics were reported about the interviewer (bias, assumptions, interest in research topic)	Page 6
9	Methodological orientation and theory	What methodological orientation was stated to underpin the study (grounded theory, content analysis etc...)	Page 9
10	Sampling	How were participants selected?	Page 3, 5, 18
11	Method of approach	How were participants approached e.g. face to face, telephone etc..	Page 5-6
12	Sample size	How many participants were in the study?	Page 5
13	Non-participation	How many participants refused to participate/dropped out?	Page 6
14	Setting of data collection	Where was the data collected: home, clinic, workplace?	Page 7

15	Presence of non-participants	Was anyone else present besides the researcher and participants?	Page 7
16	Description of sample	What are the important characteristics of the sample? E.g. demographics.	Page 9-10
17	Interview guide	Were questions, prompts, guides, provided by the authors? Was it pilot tested?	Pages 7-8
18	Repeat interviews	Were repeat interviews carried out? If yes, how many?	Page 7
19	Audio/visual recording	Did the research use audio/visual recording to collect the data?	Page 7
20	Field notes	Were field notes made during/after the interview	Pages 7-8
21	Duration	What was the duration of the interviews/focus groups?	Page 7
22	Data saturation	Was data saturation discussed?	Page 9
23	Transcripts returned	Were transcripts returned to participants for comments/correction?	Page 9
24	Number of data coders	How many data coders coded the data?	Page 9
25	Description of the coding tree	Did the researcher provide a description of the coding tree?	Page 9
26	Derivation of themes	Were themes identified in advance or derived from the data?	Page 9
27	Software	What software, if applicable, was used to manage the dataset?	Page 9
28	Participant checking	Did participants provide feedback on the findings?	Page 9
29	Quotations presented	Were participant	Pages 11-15

		quotations presented to illustrate the themes/findings? Was each quotation identified e.g. participant number?	
30	Data and findings consistent	Was there consistency between the data presented and the findings?	Pages 11-19
31	Clarity of major themes	Were the major themes clearly presented in the findings?	Pages 11-15
32	Clarity of minor themes	Is there a description of diverse cases or minor themes?	Pages 10-15

# BMJ Open

## A qualitative study of barriers to clinical trial retention in adults with recently diagnosed Type 1 Diabetes

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-022353.R1
Article Type:	Research
Date Submitted by the Author:	23-May-2018
Complete List of Authors:	Henshall, Catherine; Oxford Brookes University, Health and Life Sciences; Narendran, P; University of Birmingham, Andrews, Robert; University of Exeter Daley, Amanda; Loughborough University, School of Sport, Exercise and Health Sciences Stokes, Keith; University of Bath, Department for Health Kennedy, Amy; Royal Stoke University Hospital, Department of Diabetes and Endocrinology Greenfield, Sheila; University of Birmingham, Primary Care Clinical Sciences
<b>Primary Subject Heading</b>:	Diabetes and endocrinology
Secondary Subject Heading:	Diabetes and endocrinology
Keywords:	type 1 diabetes, exercise, physical activity, Trial retention, Clinical trials < THERAPEUTICS, participants

SCHOLARONE™  
Manuscripts

## Trial experience of people with newly diagnosed Type 1 Diabetes

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3 1 A qualitative study of barriers to clinical trial retention in adults with recently diagnosed Type 1  
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41 **Word Count:** 4322  
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52 **ABSTRACT**  
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## Trial experience of people with newly diagnosed Type 1 Diabetes

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3 22 **Objectives:** Regular physical exercise may preserve beta cell function in newly diagnosed adults with  
4  
5 23 Type 1 diabetes (T1D). However clinical trials to test this theory require the recruitment and retention  
6  
7 24 of adults with new onset T1D, which can be challenging. We sought to determine the overall  
8  
9 25 experiences of newly-diagnosed adults with T1D in an exercise study, to understand issues that  
10  
11 26 influence the retention of trial participants in such studies.  
12  
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15

16 28 **Design:** Qualitative methodology using individual face to face (n=6) and telephone interviews (n=14).  
17  
18 29 Interview transcripts were thematically analysed using the Framework Method  
19  
20  
21  
22  
23

24 31 **Setting:** The study took place at five participating UK hospitals.  
25  
26  
27  
28

29 33 **Participants:** Twenty participants, aged 19-55 years, in the Exercise for Type 1 Diabetes (EXTOD)  
30  
31 34 study were interviewed to explore their study experiences and identify motivators and deterrents  
32  
33 35 towards the study. Participants in control and intervention arms were interviewed, as were people with  
34  
35 36 T1D who had completed (n=16) and withdrawn (n=4).  
36  
37  
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40

41 38 **Results:** Participants revealed barriers and facilitators to retention; the majority were generalisable to  
42  
43 39 clinical trials of people with newly-diagnosed T1D. Coming to terms with a diagnosis of T1D, lack of  
44  
45 40 time, work pressures, level of health professional support, volume, clarity and consistency of  
46  
47 41 information and feedback and a desire for knowledge about their condition were all cited as  
48  
49 42 influencing factors to trial retention.  
50  
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53

54 44 **Conclusions:** To our knowledge, this is the first qualitative study to examine the experience of being  
55  
56 45 involved in an exercise trial by people with T1D . Findings suggest: appointments could be shorter,  
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## Trial experience of people with newly diagnosed Type 1 Diabetes

1  
2  
3 46 available outside of working hours and planned longer in advance; study information should be clear,  
4  
5 47 consistent and in electronic and paper formats; questionnaires need minimising; healthcare support  
6  
7 48 and feedback needs providing regularly; thought is required around how to support non-exercising  
8  
9 49 arm participants. These considerations may improve participant retention rates in new onset T1D  
10  
11 50 studies.

12  
13 51  
14  
15  
16 52 **Keywords:** Type 1 diabetes; Exercise; Physical Activity; Trial Retention; Clinical Trials;  
17  
18 53 Participants; Adults; Diagnosis  
19  
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21 54

22  
23  
24 55 **Strengths and limitations of this study**

- 25  
26 56
- 27 • A qualitative, interview study was undertaken to explore, in-depth, the experiences of people  
28 with type 1 diabetes who were participating in an exercise study.
  - 29 57
  - 30 58 • The study was multi-site, taking place at five participating hospital trusts across the UK.
  - 31 59
  - 32 59 • Rigorous data collection and analysis techniques were undertaken, using the Framework  
33 approach.  
34 60
  - 35 60
  - 36 61 • Ethnicity excluded as a purposive sampling criterion resulting in only White participants  
37 being represented.  
38 62
  - 39 62
  - 40 63 • To our knowledge, this is the first qualitative study to examine people with T1D experiences  
41 of being involved in an exercise trial.  
42 64  
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51 67 **INTRODUCTION**

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54 68 Type 1 diabetes (T1D) is a chronic autoimmune condition characterised by immune mediated  
55  
56 69 destruction of insulin producing pancreatic beta cells<sup>1</sup>. Significant numbers of  $\beta$  cells are present at



## Trial experience of people with newly diagnosed Type 1 Diabetes

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2  
3 70 the time of diagnosis <sup>2</sup>, and preservation of  $\beta$ -cell function is associated with significant benefits for  
4  
5 71 people with T1Ds. Interventions that can preserve residual  $\beta$ -cell function in new-onset T1D are  
6  
7 72 needed.  
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11  
12 74 In animal models of Type 1 and Type 2 diabetes (T2D), healthy humans, and in people with impaired  
13  
14 75 glucose tolerance with T2D, regular exercise has been shown to preserve  $\beta$ -cell function<sup>3</sup>. These  
15  
16 76 findings have not been tested in people with T1D and there is thus a need for a prospective clinical  
17  
18 77 trial to test the hypothesis that exercise preserves  $\beta$ -cell function in people newly diagnosed with T1D.

19  
20  
21 78 The EXTOD (Exercise for T1D) study was a pilot study undertaken to explore whether exercise can  
22  
23 79 preserve beta cell function in adults newly diagnosed with T1D. In designing this study, we had to  
24  
25 80 bear in mind that the incidence rate of T1D is low, and recruitment of people with T1D to clinical  
26  
27 81 trials is challenging <sup>4-6</sup>. Other studies have shown recruitment rates as low as 17% <sup>4</sup>. This means that  
28  
29 82 retaining people with newly diagnosed T1D who are recruited to studies is even more important. In  
30  
31 83 studies of immunotherapeutic agents for T1D, drop out rates are 12-14%<sup>7-8</sup>; however higher rates  
32  
33 84 have been reported for exercise studies. In a meta-analysis of unsupervised exercise programmes for  
34  
35 85 people with T2D, 20% of studies had a dropout of > 20%, 32% a dropout of 10–20%, and 48% a  
36  
37 86 dropout of < 10% <sup>9</sup>.

38  
39  
40 87 Barriers to participation in clinical trials are well documented <sup>10</sup>, although no studies have looked at  
41  
42 88 barriers to recruitment in people with T1D. There are very few studies that have looked at how to  
43  
44 89 improve retention rates of people with T1D in a clinical randomized controlled trial (RCT). Those  
45  
46 90 studies that have been done have concentrated on strategies to improve retention rather than barriers  
47  
48 91 to retention <sup>11</sup>. No studies have looked at barriers to retention in people newly diagnosed with T1D.  
49  
50 92 We wished to address this important deficit by qualitatively exploring the experiences of people with  
51  
52 93 newly diagnosed T1D who participated in a recently completed exercise and T1D study <sup>12</sup>. Here we  
53  
54 94 report our findings from a qualitative study of barriers to clinical trial retention in adults with recently  
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## Trial experience of people with newly diagnosed Type 1 Diabetes

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2  
3 95 diagnosed T1D. We have not reported other findings from the EXTOD study, which are reported  
4  
5 96 separately<sup>13,14</sup>.

7 97 **METHODS**

10 98 **Setting, access and recruitment**

13 99 Study participants were from the EXTOD study, whose protocol has been described previously<sup>12</sup>. In  
14  
15 100 brief, all people aged between 16 and 60 years, diagnosed with T1D in the previous three months,  
16  
17 101 from 19 UK hospital sites, were invited to participate. The EXTOD study explored the barriers and  
18  
19 102 benefits of exercise in adults with newly diagnosed T1D. The hypothesis being tested by the EXTOD  
20  
21 103 study was that exercise preserved beta cell function in adults recently diagnosed with T1D. EXTOD  
22  
23 104 had two phases. Phase 1 consisted of a qualitative study to determine attitudes and barriers to  
24  
25 105 exercise in people with newly diagnosed T1D<sup>13</sup>. Phase 2 was a pilot RCT to assess uptake,  
26  
27 106 intervention adherence, drop-out rates, and rate of uptake in the usual care group during a 12 month  
28  
29 107 exercise intervention (where the participants came from for this study).

31 108 At the time of recruitment to the pilot RCT (phase 2) study, all people with T1D received participant  
32  
33 109 information leaflets and provided informed consent to potentially take part in an interview to explore  
34  
35 110 their experience of being involved in the pilot RCT. Of the 60 participants who took part in the pilot  
36  
37 111 RCT, twenty participants from five participating sites (Birmingham, Leeds, Bristol, Gloucester,  
38  
39 112 Taunton) were later selected using purposive sampling to ensure variety and diversity in terms of their  
40  
41 113 key study characteristics<sup>15</sup>. Participants were sampled in relation to their age, gender, study arm  
42  
43 114 (intervention/control) and study status (completed/withdrawn) to ensure that an even spread of  
44  
45 115 participants across the key characteristics were sampled. Similarly the sites were selected to allow a  
46  
47 116 purposeful sampling of geographical areas participating in the EXTOD study (teaching hospitals  
48  
49 117 versus district general hospitals). Selected participants were sent a letter at the end of the pilot RCT,  
50  
51 118 informing them that they would be contacted by the EXTOD team. This was followed, a week later,  
52  
53 119 by a phone-call from a member of the EXTOD team (nurse or doctor) to check they were happy to be  
54  
55 120 interviewed. If willing, they were then telephoned by the researcher (CH), who has a nursing

## Trial experience of people with newly diagnosed Type 1 Diabetes

1  
2  
3 121 background and is an experienced qualitative researcher (though she had not previously undertaken  
4  
5 122 any research in this area), to arrange a suitable time and date for her to undertake the interview. CH  
6  
7 123 had had no contact with participants prior to this and participants were unaware of the researcher's  
8  
9 124 background. All participants agreed to be interviewed.

10  
11 125  
12

13  
14 126 This study had ethical approvals from The West Midlands and Solihull Research Ethics Committee  
15  
16 127 (10/H1206/4).  
17  
18

19 128  
20

21  
22 129 **Patient Involvement**

23  
24 130 The research question was derived from people with T1D attending clinic and asking clinicians about  
25  
26 131 any benefits and barriers to exercise, as they were aware that much work had been undertaken on this  
27  
28 132 topic in people with T2D, but not in people with T1D. This led to the formulation of the research  
29  
30 133 question and an application for funding to undertake this research. People with T1D were involved in  
31  
32 134 the study design from the outset, as the researchers presented the study proposal to them, and asked  
33  
34 135 for any comments relating to it (approximately seven people with T1D were involved). Issues relating  
35  
36 136 to the conduct of the study, such as the potential burden of the exercise intervention to participants,  
37  
38 137 were also discussed and any feedback was incorporated into the study design. People with T1D also  
39  
40 138 contributed to the study conduct by sitting on the study management committee and helping with  
41  
42 139 study oversight, including helping to develop approaches to improve study recruitment (three people  
43  
44 140 with T1D were involved). Study findings for phase 2 of the study were fed back to participants  
45  
46 141 through an informal feedback evening where the findings were presented. This was well received by  
47  
48 142 the participants. In addition, a summary of findings was posted to participants.  
49

50  
51 143  
52

53  
54 144 **Data collection**  
55  
56  
57  
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59  
60

## Trial experience of people with newly diagnosed Type 1 Diabetes

1  
2  
3 145 Participants at the hospital where the researcher was based (Birmingham) were given the option of  
4  
5 146 being interviewed face-to-face at the hospital , or by telephone. The remaining participants were all  
6  
7 147 interviewed by telephone, due to financial, time and travel constraints. All interviews were carried out  
8  
9 148 with only the participant and CH present.

10  
11 149

12  
13  
14 150 Interviews were carried out by CH, using a structured topic guide (Table 1) that was developed in  
15  
16 151 consultation with the EXTOD researchers. The interviews lasted between 20 to 50 minutes. No repeat  
17  
18 152 interviews were conducted. Areas for discussion included levels of health professional support,  
19  
20 153 information provided about diet and exercise and issues relating to recruitment and follow up. All  
21  
22 154 interviews were digitally recorded and transcribed verbatim by a local transcription company.  
23  
24

25 155

26 156

27 157

28 158 **Table 1: Topic Guide for Interview Study**

<b>Openers</b>	If I could start by asking you how long ago you took part in the study? How did you find the experience?
<b>Diet and Exercise Information</b>	How appropriate was the advice about diet and exercise in relation to its content and volume? Do you feel being recruited to the study so soon after diagnosis was a good thing or would you have preferred more time? When would have been an appropriate time? How well were able to take in the information you were given? Would it have been helpful to see the dietician again, or do you feel that once was enough? Did you refer to the study information booklet? If so, how helpful was the information booklet? Which sections of the booklet particularly helpful or unhelpful? Do you use the booklet as a reference guide now? Did any aspects of your diet change following looking at the information booklet? Can you think of any better ways in which the information could have been delivered?
<b>Health Professional Support</b>	How well supported did you feel in terms of the clinical support you received? Did you feel you more or less well supported through being on the trial? Do you feel being in the trial was better or worse in terms of the number of doctors/nurses you saw? Why?

## Trial experience of people with newly diagnosed Type 1 Diabetes

	<p>Were you happy seeing the same nurse all the way through the trial or would you have preferred more variety? Did you mind no longer seeing the nurse you saw when you were diagnosed?</p> <p>Do you mind not seeing these study doctors/nurses on a regular basis now?</p> <p>How well balanced were the follow up visits in terms of the health professional you saw? Would you have preferred more/less visits with a doctor/nurse etc...Or do you feel it was the right amount of time with each?</p> <p>Overall, how well supported by the doctors and nurses did you feel?</p>
<b>Recruitment and Follow Up</b>	<p>Where did you first hear about the trial from? Who approached you?</p> <p>What appealed to you about taking part in the study in the first place? What were your reasons?</p> <p>Was there anything that put you off taking part in the study?</p> <p>How easy to complete and understand were the questionnaires you received?</p> <p>During the trial you were required to have extra blood tests. How did you feel about having the extra bloods?</p> <p>How much did you feel the follow up visits were focused on you and how much did you feel they were focused on the trial and form filling etc...Was this appropriate or could it be weighted differently?</p> <p>Would you have preferred most of the follow up visits to have taken place face to face or over the phone?</p> <p>Can you describe whether being on the study affected your confidence levels in terms of undertaking exercise?</p> <p>What were your reasons for leaving the study?</p> <p>Why did you choose to continue/discontinue with the 5year FU as part of the study?</p>
<b>Motivational Interviewing (intervention group only)</b>	<p>How useful do you feel the extra support you were given by the nurse about managing your diabetes and exercising was? What were the pros and cons of talking to the nurse about this?</p> <p>Would it have been helpful to have weekly phone calls from the nurse to check on how you were getting on?</p> <p>Did the amount of exercise you undertook change as a result of these talks with the nurse or did it stay the same?</p> <p>Did the type of exercise you undertook change or stay the same following a) diagnosis and b) the intervention?</p> <p>How much physical activity were you carrying out before your diagnosis compared to a) during the study and b) now? Has your exercise levels been maintained post-study?</p> <p>Did you feel more or less confident about carrying out exercise following the intervention with the nurse?</p> <p>What more could have been done to encourage you to exercise?</p> <p>What sort of approach might have worked for you to help you to exercise?</p> <p>Some participants did not make their exercise target. Can you think how we could help them reach this target?</p> <p>What methods did you use to increase your exercise levels?</p>
<b>Future Development of Study</b>	<p>If there was one thing we could do to make the study easier for you to take part in what would it be?</p> <p>We are planning to undertake a larger scale study similar to the one you have taken part in. What sort of things would you change about the study that might make people want to take part in it more?</p> <p>Overall, what did you feel was good or bad about taking part in the study?</p>

## Trial experience of people with newly diagnosed Type 1 Diabetes

	Do you think you would be more or less likely to participate in clinical trials following this experience?
--	--

159

160 **Data Analysis**

161 Data analysis was carried out during the interview period to enable the interview process to be shaped  
162 by the emerging data themes and to identify when saturation had been reached. For example, some  
163 participants in the early interviews spoke of how they had struggled to come to terms with their new  
164 T1D diagnosis. As a result subsequent interviews explored this area in more depth, focusing on the  
165 impact this had on their experience of participating in the EXTOD study. An inductive approach to  
166 data analysis was taken and themes were derived from the interview dataset. The pre-determined  
167 topic areas set out in the topic guide (Table 1) such as ‘health professional support’ and ‘recruitment  
168 and follow-up’ guided the analysis process as much of the data collected focused on these topic areas,  
169 enabling the researchers to elicit information that was relevant to the study question. Data was coded  
170 by CH and was inserted into a framework analysis matrix Excel spreadsheet, to enable data ordering  
171 and synthesis, whilst retaining the meaning and feeling of the interviewees’ words<sup>16</sup>. Themes were  
172 developed by CH by reading and rereading the transcripts and these themes were then agreed during  
173 discussions with research team members (CH, PN and SG). The interviews were then analysed using  
174 thematic analysis<sup>17</sup>. Transcripts were not returned to participants to comment on during this process.

175

176 **RESULTS**177 **Participants**

178 Twenty participants were interviewed; six face to face and fourteen by telephone (Table 2).  
179 Participants were recruited from all five participating sites; eleven were male, ages ranged from 19-55  
180 and all were of white British ethnic origin. Thirteen had been allocated to the intervention group and  
181 seven to the usual care comparator. Sixteen participants had completed EXTOD, whilst four had

## Trial experience of people with newly diagnosed Type 1 Diabetes

182 withdrawn for reasons including work commitments, a cancer diagnosis, and difficulties accepting  
 183 their diabetes diagnosis.

184

185 **Table 2: Characteristics of participants**

Participant	Gender	Centre	Treatment arm	Complete/with drew	Interview format
1	Female	Birmingham	Intervention	Completed	Telephone
2	Male	Birmingham	Control	Completed	Face to face
3	Male	Birmingham	Intervention	Completed	Face to face
4	Female	Birmingham	Intervention	Withdrew	Telephone
5	Male	Leeds	Intervention	Withdrew	Telephone
6	Female	Leeds	Control	Withdrew	Telephone
7	Female	Birmingham	Intervention	Completed	Face to face
8	Female	Birmingham	Intervention	Completed	Face to face
9	Male	Birmingham	Control	Completed	Face to face
10	Male	Birmingham	Control	Completed	Telephone
11	Male	Birmingham	Intervention	Completed	Telephone
12	Male	Taunton	Intervention	Completed	Telephone
13	Male	Gloucester	Control	Completed	Telephone
14	Female	Bristol	Intervention	Completed	Telephone
15	Male	Bristol	Control	Completed	Telephone
16	Male	Bristol	Intervention	Completed	Telephone
17	Male	Bristol	Control	Withdrew	Telephone
18	Female	Leeds	Intervention	Completed	Telephone
19	Female	Birmingham	Intervention	Completed	Face to face
20	Female	Taunton	Intervention	Completed	Telephone

186

187

## Trial experience of people with newly diagnosed Type 1 Diabetes

188 **Themes**

189 The interviews yielded data on five main themes and these help formulate the barriers and facilitators  
 190 to trial participation (Table 3). These themes were: study paperwork; feedback; barriers to continued  
 191 participation; coming to terms with diagnosis of T1D; effect of allocated arm.

192  
 193 **Table 3: Facilitators and barriers to continued Clinical Trial Participation in People with Type 1**  
 194 **Diabetes Mellitus**

Facilitators
<ul style="list-style-type: none"> <li>• Consistency and continuity of health professional support</li> <li>• Clear, detailed and relevant information about diabetes and its management</li> <li>• Availability of both paper and electronic information and documentation</li> <li>• Reduction in volume of study documentation</li> <li>• Flexible access to trial facilities outside of normal working hours</li> <li>• Appointments scheduled in advance to allow for planning around work and social lives</li> <li>• Early feedback of trial findings</li> </ul>
Barriers
<ul style="list-style-type: none"> <li>• Time</li> <li>• Work pressure</li> <li>• Travelling to appointment</li> <li>• Length of visits</li> <li>• Length of study</li> <li>• Coming to terms with diagnosis</li> <li>• Being able to maintain exercise levels</li> <li>• Being allocated to the control (non exercising arm)</li> </ul>

195  
196  
197 **Study Paperwork**

198 Two main subthemes emerged within the ‘study paperwork’ theme; these were study information and  
 199 study questionnaires.

200  
201 *Study information*



## Trial experience of people with newly diagnosed Type 1 Diabetes

1  
2  
3 202 The volume, clarity and consistency of information provided were important in determining how well  
4  
5 203 informed participants' felt about their diabetes and its management. Though a few participants felt  
6  
7 204 they were given too much information, most felt that although there was a lot of information, it was  
8  
9 205 useful, relevant and necessary so soon after diagnosis. Generally the information was cited as  
10  
11 206 interesting, manageable and straightforward. Others spoke of how they valued the repetition of some  
12  
13 207 information, as it meant they could fully absorb it.

14  
15 208 *'To be honest I thought it was perfect...I was sort of drip-fed information throughout the year really,*  
16  
17 209 *and it was very good...After...The shock of being told you're Type 1 diabetic...I found it very good*  
18  
19 210 *and the team was extremely helpful.'* EXTOD 12 (Male, Taunton)

20  
21  
22 211

23  
24  
25 212 Most participants were happy receiving paper information, finding it easy to read and acknowledging  
26  
27 213 that not everyone had Internet access. Others, especially younger participants, stated they would have  
28  
29 214 preferred digital information, such as Apps, to access information faster. One participant suggested  
30  
31 215 having a centralised webpage specific to the hospital's diabetes unit, with links to different diabetes  
32  
33 216 resources on it. Participants supplemented the trial information with other resources, such as the  
34  
35 217 'Carbs and Cal' book<sup>18</sup>. Others used digital resources, such as the 'Carbs and Cal' or 'Fitness Pal'  
36  
37 218 apps and online information<sup>18</sup>.

38  
39  
40 219 *'Being a bit of a technology geek, I went with the app which is the Carbs and Cals app...It will give*  
41  
42 220 *you a particular breakfast, like Alpen...and then it will show you...the size of portion that you're*  
43  
44 221 *supposed to have, and how much insulin you're supposed to take.'* EXTOD 2 (Male, Birmingham)

45  
46  
47 222

48 223 *Study questionnaires*

49  
50 224 Most participants felt the study paperwork was too long and time-consuming, 'switching off' from it  
51  
52 225 as a result, as it got in the way of work and personal lives. Much paperwork was questionnaires  
53  
54 226 relating to diet, exercise and quality of life that were completed at the study visit. Participants felt that  
55  
56 227 although the paperwork was generally easy to complete and understand, it could also be repetitive,

## Trial experience of people with newly diagnosed Type 1 Diabetes

1  
2  
3 228 confusing and contradictory, containing irrelevant, non-specific questions, which were hard to relate  
4  
5 229 and respond to.

6  
7 230 *'I remember always getting given the questionnaire sheet when I was having my bloods done. And I*  
8  
9 231 *could just never fill it in. It used to be like – I used to say to my dad can you ask my questions and*  
10  
11 232 *then I could do it, but it did go on for quite a while... And it was the same the second time I did it as*  
12  
13 233 *well, and I was like I don't know what to put for these questions again. It seemed like I was doing the*  
14  
15 234 *same thing.'* EXTOD 19(Female, Birmingham)

16  
17 235

18  
19  
20 236 Feedback

21  
22  
23 237 Some participants voiced disappointment at receiving little trial feedback, stating that the opportunity  
24  
25 238 for feedback had incentivised them to join the trial, as a way of finding out about their diabetes and  
26  
27 239 also that they wanted to learn more about the long term trial outcomes.

28  
29  
30 240 *'It would be good to have some follow-up information...I wasn't quite sure how my fitness level was*  
31  
32 241 *affected....And I never got to find out if it actually improved.'* EXTOD 1(Female, Birmingham)

33  
34 242

35  
36  
37 243 Barriers to continued participation

38  
39  
40 244 Seventeen of the 58 participants who were randomised into the original EXTOD study withdrew  
41  
42 245 before the end of the study. We thus sought to understand why this might have happened.

43  
44  
45 246

46  
47 247 Participants described practical barriers as the most likely reasons for dropping out. These included  
48  
49 248 time and work pressures, dislike of blood tests, travelling to appointments, the long study duration,  
50  
51 249 volume of visits and moving away.

52  
53  
54 250 *'I'm not bothered for taking blood or doing injections or anything like that...But I can remember*  
55  
56 251 *feeling bothered by that at the time. I think because I was very ill, really, still, and still quite fragile*

## Trial experience of people with newly diagnosed Type 1 Diabetes

1  
2  
3 252 ... I can remember that upsetting me...Because it was a study and because I didn't have to do it...If  
4  
5 253 you volunteered to have a blood test and it takes a few times for them to take the blood, it's kind of  
6  
7 254 like putting yourself through something difficult that you didn't really need to do.' EXTOD 6(Female,  
8  
9 255 Leeds)

10  
11 256  
12  
13 257 The long study duration also deterred many participants, who felt it was too long to fully commit to,  
14  
15 258 meaning they became less vigilant at attending appointments or completing study documentation due  
16  
17 259 to the repetition involved.

18  
19 260 'It's quite long. I think that was quite daunting. It turned out to not really be an issue, but because  
20  
21 261 it's something that I could kind of blend into my lifestyle quite a lot. Because I suppose it didn't really  
22  
23 262 require any prolonged visits to the clinic or anything because it was mostly just things that I could do  
24  
25 263 myself. But initially that was a bit daunting because it's a year.' EXTOD 16 (Male, Bristol)

26  
27 264  
28  
29 265 For most, committing to the EXTOD study had proved difficult, due to the time it required off work.  
30  
31 266 This led to difficulties for participants in ensuring they could always attend appointments and  
32  
33 267 sometimes proved costly, due to having to take unpaid leave for study visits.

34  
35 268 "The time that you're having to have off work...Often it's unpaid leave so obviously that can be quite  
36  
37 269 difficult." EXTOD 18(Female, Leeds)

38  
39 270  
40  
41 271 These time pressures had led to two of the interviewed participants withdrawing from EXTOD prior  
42  
43 272 to completion. Solutions to these problems suggested by participants -who had both withdrawn and  
44  
45 273 remained in the study - included offering more flexible appointment times and planning clinic visits  
46  
47 274 further in advance so there was more time to plan around them.

48  
49 275 'I left...Because I didn't have enough time...The study is of such a long duration and I just found that  
50  
51 276 too challenging with work...If you had appointments at eight o'clock in the evening every time you  
52  
53 277 needed me then so be it...I have to do a hell of a lot of juggling in order to fit that sort of stuff in.'  
54  
55 278 EXTOD 17(Male, Bristol)

## Trial experience of people with newly diagnosed Type 1 Diabetes

279

280 Coming to terms with diagnosis of T1D

281 Some participants spoke of how they had struggled to come to terms with their T1D diagnosis, with  
282 one participant citing this as their reason for withdrawing from EXTOD. For this participant, her  
283 difficulties coping emotionally with her diagnosis had prompted her doctors to advise her to  
284 withdraw.

285 *“Don’t think it kind of really sank in as to what I’d been diagnosed with... It had kind of hit me and I  
286 wasn’t really dealing with having it...I wasn’t taking my insulin and checking my levels as much...The  
287 doctors...Felt that it was best that I was taken off it.” EXTOD 4(Female, Birmingham)*

288

289 Effect of allocated arm

290 Some participants, who had been allocated the exercise intervention, spoke of difficulties maintaining  
291 the level of exercise expected of them, due to lack of motivation or the extra time it took.

292 *‘I think a year in it seemed to get a little bit “Oh God I’ve been doing this for a year now”...A year’s  
293 a long time... Because towards the end as well, it was like you had to come in and then I had to do the  
294 gym thing, and it was kind of like...“oh this is getting really laborious”.’ EXTOD 2(Male,  
295 Birmingham)*

296

297 Others, in the usual care comparator group, spoke of how this discentivised them from remaining in  
298 EXTOD as they were not receiving the exercise benefits they had hoped for.

299 *“The sort of people that...Take part...Are often similar to me in kind of quite wanting to do the  
300 exercise, and presumably about half of the time you get randomised into not doing the exercise. And I  
301 don’t know whether that’s off-putting as well.” EXTOD 16(Male, Bristol)*

302

303 **DISCUSSION**

304 This is the first study to examine the experiences of people with T1D taking part in an exercise  
305 intervention trial. The findings have highlighted issues that should be considered when designing  
306 clinical trials involving this population group. Clinical trials which reflect the needs, wants and

## Trial experience of people with newly diagnosed Type 1 Diabetes

1  
2  
3 307 preferences of participants can lead to improvements in retention rates, statistical power and, in the  
4  
5 308 longer term, to studies with more credible findings. The findings suggest that timing is an important  
6  
7 309 consideration for many participants. Many may be offered trial entry shortly after their condition's  
8  
9 310 onset and may be experiencing multiple health and lifestyle changes and struggling to come to terms  
10  
11 311 with their diagnosis of T1D. This highlights the need for sensitive communication of information  
12  
13 312 from health professionals when introducing clinical trials to adults with T1D, as they may be  
14  
15 313 experiencing tensions between not wanting to 'become' their new illness or allow it to govern them,  
16  
17 314 whilst reconciling that they need to be adaptable to their illness if they are going to feel well again<sup>19-</sup>  
18  
19 315 <sup>20</sup>. The disappointment of some participants at being allocated the usual care group also highlights the  
20  
21 316 need for a clear explanation of equipoise and other clinical trials terminology, so participants can  
22  
23 317 make informed treatment decisions, minimising the potential for withdrawal rates after  
24  
25 318 randomisation<sup>21</sup>. Additional measures that could help with this are offering the intervention at the end  
26  
27 319 of the study or randomising more to the exercise arm than the control arm, to enable more participants  
28  
29 320 access to the intervention.

30  
31 321  
32 322 The study has illustrated the need for the transmission of clear, relevant and useful information to  
33  
34 323 clinical trial participants. Participants showed preferences for a wide-range of delivery modes,  
35  
36 324 including paper formats, websites, apps and Internet forums. The use of appropriate, accessible media  
37  
38 325 to convey information effectively and engage with participants is dependent on individual preferences  
39  
40 326 and may be influenced by factors such as age, gender and income<sup>22</sup>. The popularity of Apps and  
41  
42 327 multimedia technologies amongst participants indicates that these modes of information delivery  
43  
44 328 should be incorporated specifically into trials with T1D participants, who are likely to be a younger,  
45  
46 329 more technologically minded population group than trials with T2D participants. Future trial designs  
47  
48 330 could offer paper and electronic information so participants' can utilise their preferred resource.  
49  
50 331 Similarly, when collecting data, a range of methods could be employed, including paper  
51  
52 332 documentation, spreadsheets, phone apps, emails and websites. Demonstrating versatility and  
53  
54 333 flexibility in data collection techniques may help motivate participants to complete study  
55  
56 334 documentation that they might otherwise omit. The importance of providing regular study feedback to

## Trial experience of people with newly diagnosed Type 1 Diabetes

1  
2  
3 335 participants should also be considered, through letters, emails and presentations, so that their  
4  
5 336 contribution is acknowledged and valued<sup>23</sup>.  
6  
7 337  
8  
9 338 Finally, the interview findings highlighted that practicalities such as work pressures, time  
10  
11 339 commitments and geographical location influenced participants' ability to commit to the trial. T1D  
12  
13 340 onset usually occurs at a young age, with most people being diagnosed before 35<sup>24</sup>. As a result, people  
14  
15 341 with T1D are likely to have busy lives incorporating work, family and social engagements, making  
16  
17 342 committing to a clinical trial difficult. This is verified by the commonest reason cited for the high  
18  
19 343 dropout rate (29%) from EXTOD being time and work commitments. To rectify this, more flexible  
20  
21 344 study visit times could be offered, with the option of attending outside normal working hours, such as  
22  
23 345 evenings and weekends. Additionally, the provision of a timetable of scheduled appointments at the  
24  
25 346 study outset would allow participants to plan for them. Improved hospital transport links could also  
26  
27 347 facilitate ease of study attendance<sup>25</sup>. By incorporating a flexible approach to these practical barriers,  
28  
29 348 participants will experience less difficulty in complying with study visits, improving retention rates.  
30  
31 349 Consideration should also ensure that the exercise intervention can be integrated into people's  
32  
33 350 lifestyles, without adding to their pressurised schedules. This could be done by providing a range of  
34  
35 351 exercise options, in a range of locations and within a realistic timeframe, to minimise the likelihood of  
36  
37 352 participants becoming over-faced by the extra commitment they have taken on.  
38  
39 353  
40  
41 354 Many of the challenges to clinical trial retention in people with T1D are similar to the challenges  
42  
43 355 facing the general population who are recruited to clinical trials<sup>26-30</sup>. The issues and challenges  
44  
45 356 participants faced, such as the long study duration, difficulties completing documentation and time  
46  
47 357 pressures, are also likely to be challenges for the general clinical trials population, including T2D.  
48  
49 358 However, this study has identified that although many of these trial related issues are not specific to  
50  
51 359 T1D populations, the reasons for these issues are likely to be different. For example, people with T1D  
52  
53 360 or T2D may report that time pressures prevent them from committing to a clinical trial. However,  
54  
55 361 whilst for the T1D participant, time pressures may stem from work priorities, the T2D participant time  
56  
57 362 pressures may stem from regularly caring for grandchildren. By understanding more about the reasons

## Trial experience of people with newly diagnosed Type 1 Diabetes

1  
2  
3 363 behind these barriers to trial recruitment and retention, trials can be designed to accommodate and  
4  
5 364 facilitate the wants and needs of these different groups. The average age of participants entering  
6  
7 365 clinical trials is over 50 years of age<sup>28-31</sup>. Whilst there is growing evidence that T1D is diagnosed  
8  
9 366 throughout adult life<sup>32,33</sup> the mean age of the randomised EXTOD participants was 32 years,  
10  
11 367 suggesting that trial retention considerations should focus on needs of younger adult populations. This  
12  
13 368 younger age-group is likely to face more difficulties in adhering to rigid time schedules and  
14  
15 369 appointments due to added work, family and social pressures. This is important for clinicians and  
16  
17 370 researchers to acknowledge, allowing them to design T1D studies that will facilitate trial recruitment  
18  
19 371 and retention, by offering more flexible appointment times, out-of-hours services and realistic,  
20  
21 372 manageable exercise schedules. These practical solutions are important considerations for retaining  
22  
23 373 participants in clinical trials and must be valued if rich and full trial datasets are to be obtained. These  
24  
25 374 considerations may also have some relevance for T2D populations, with the average age of onset for  
26  
27 375 this disease getting younger<sup>33,34</sup>. When considering study design, thought must be given to how to  
28  
29 376 increase recruitment, as well as how to make the study experience appealing to participants once they  
30  
31 377 have consented. By paying attention to the participant's perspective, the chances of retaining  
32  
33 378 participants for the study duration will increase, improving trial outcomes and participant satisfaction  
34  
35 379 with trial entry.

36  
37 380381 **Strengths and limitations**

382 The interview participants were selected from five UK hospitals, increasing the transferability of the  
383 findings to a range of settings. Participants were purposively sampled, stratifying them according to  
384 age, gender, randomisation arm and whether they had completed or withdrawn from the study. This  
385 enabled a diverse and comprehensive collection of narratives to be gathered and analysed, enhancing  
386 the trustworthiness of the findings. However, although 12% of EXTOD participants recruited were  
387 non-White, none of the participants recruited to the qualitative study were non-White. This lack of  
388 representation is due to our exclusion of ethnicity as a criterion in our purposive sampling. Although,  
389 we did not purposefully exclude non-White participants from the sample, the likely reason for their  
390 lack of inclusion is because T1D is far more common in White populations than other ethnic groups<sup>35</sup>.

## Trial experience of people with newly diagnosed Type 1 Diabetes

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2  
3 391 Additionally, many of the geographical locations we recruited from had a White population of over  
4  
5 392 84%<sup>36-38</sup>. Despite this, including ethnicity in our purposeful sample could have ensured that non-  
6  
7 393 White populations were represented. In addition, due to the interview participants being situated  
8  
9 394 around the UK, most interviews were conducted by telephone. However, where possible, participants  
10  
11 395 were given the choice of being interviewed face-to-face or by telephone, allowing them to choose the  
12  
13 396 setting they found most relaxing, thus increasing opportunity for open dialogue between interviewees  
14  
15 397 and researcher. The fairly even split between participants choosing face-to-face and telephone  
16  
17 398 interviews suggests that providing a choice of setting may increase recruitment and retention to trials,  
18  
19 399 giving participants the opportunity to select their most comfortable environment.

400

401 **CONCLUSION**

402 To our knowledge, this is the first qualitative study to examine T1D participants' experiences of being  
403 involved in a clinical trial. Although people may be initially motivated to enter clinical trials for  
404 reasons such as altruism and a desire for information, practical factors such as work and time  
405 constraints, study duration and financial difficulties often act as deterrents for remaining on trials.  
406 Though these issues in themselves are not unique to the T1D population, the *reasons* for these issues  
407 are likely to be different. These reasons need considering when designing T1D clinical trials, to  
408 ensure that appropriate modifications are built into the trial design to enable people with T1D to  
409 participate with minimal disruption to their lives.

410

411 The study findings have highlighted that differences do exist between T1D participants and the  
412 general clinical trials population. Firstly, despite T1D increasingly being diagnosed in adult life, the  
413 younger adult age of people with T1D at recruitment may make it harder for them to commit to  
414 clinical trials due to increased work, family and social pressures; this was verified by study  
415 participants. Secondly, the study has indicated that using multimedia technology might benefit T1D  
416 participants, who are used to handling information electronically. It has highlighted that to increase  
417 retention to T1D trials, improvements to trial design are required. This can be done through providing



Trial experience of people with newly diagnosed Type 1 Diabetes

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3 418 flexible access to services, clear and relevant study information, documentation and feedback, as well  
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5 419 as consistent healthcare support.  
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45 436 **COMPETING INTERESTS STATEMENT**

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48 437 None declared.  
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54 439 **REPORTING GUIDELINES**

Trial experience of people with newly diagnosed Type 1 Diabetes

440 The COREQ reporting guidelines were followed.

441

#### 442 **DATA SHARING STATEMENT**

443 The datasets used and/or analysed during the current study are available from the corresponding  
444 author on reasonable request.

445

#### 446 **AUTHOR CONTRIBUTIONS**

447 All authors (CH, PN, RA, AD, KS, AK, SG) contributed substantially to conception and design, or  
448 acquisition of data, or analysis and interpretation of data. All authors drafted or revised the article  
449 critically for important intellectual content. All authors gave final approval of the version to be  
450 published.

451

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Table 1: COREQ Checklist for manuscript ID bmjopen-2018-022353

Checklist number	Item	Description	Location in manuscript (page number)
1	Interviewer/facilitator	Which author conducted interview/focus group	Page 6
2	Credentials	What were the researcher's credentials	Page 1
3	Occupation	What was their occupation at the time of the study	Page 6
4	Gender	Was the researcher male or female	Page 6
5	Training	What experience or training did the researcher have	Page 1, page 6
6	Relationship established	Was a relationship established prior to study commencement	Page 6
7	Participant knowledge of researcher	What did participants know about the researcher	Page 6
8	Interviewer characteristics	What characteristics were reported about the interviewer (bias, assumptions, interest in research topic)	Page 6
9	Methodological orientation and theory	What methodological orientation was stated to underpin the study (grounded theory, content analysis etc...)	Page 9
10	Sampling	How were participants selected?	Page 3, 5, 18
11	Method of approach	How were participants approached e.g. face to face, telephone etc..	Page 5-6
12	Sample size	How many participants were in the study?	Page 5
13	Non-participation	How many participants refused to participate/dropped out?	Page 6
14	Setting of data collection	Where was the data collected: home, clinic, workplace?	Page 7

15	Presence of non-participants	Was anyone else present besides the researcher and participants?	Page 7
16	Description of sample	What are the important characteristics of the sample? E.g. demographics.	Page 9-10
17	Interview guide	Were questions, prompts, guides, provided by the authors? Was it pilot tested?	Pages 7-8
18	Repeat interviews	Were repeat interviews carried out? If yes, how many?	Page 7
19	Audio/visual recording	Did the research use audio/visual recording to collect the data?	Page 7
20	Field notes	Were field notes made during/after the interview	Pages 7-8
21	Duration	What was the duration of the interviews/focus groups?	Page 7
22	Data saturation	Was data saturation discussed?	Page 9
23	Transcripts returned	Were transcripts returned to participants for comments/correction?	Page 9
24	Number of data coders	How many data coders coded the data?	Page 9
25	Description of the coding tree	Did the researcher provide a description of the coding tree?	Page 9
26	Derivation of themes	Were themes identified in advance or derived from the data?	Page 9
27	Software	What software, if applicable, was used to manage the dataset?	Page 9
28	Participant checking	Did participants provide feedback on the findings?	Page 9
29	Quotations presented	Were participant	Pages 11-15

		quotations presented to illustrate the themes/findings? Was each quotation identified e.g. participant number?	
30	Data and findings consistent	Was there consistency between the data presented and the findings?	Pages 11-19
31	Clarity of major themes	Were the major themes clearly presented in the findings?	Pages 11-15
32	Clarity of minor themes	Is there a description of diverse cases or minor themes?	Pages 10-15