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Title: ‘Is Insulin Right for Me?’: feasibility of a pilot randomised controlled trial and acceptability of a web-based intervention to reduce psychological barriers to insulin therapy among adults with type 2 diabetes

Running title: Reducing barriers to insulin: pilot randomised control trial

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Conflicts of Interest

EH-T has undertaken research funded by an unrestricted educational grant from Abbott Diabetes Care, AstraZeneca, and Sanofi; received speaker fees from Novo Nordisk and Roche to Australian Centre for Behavioural Research in Diabetes (ACBRD); and served on an advisory board for AstraZeneca. JF has received unrestricted educational grants for research support from Roche, Sanofi, and Medtronic. TS serves on advisory boards for Novo Nordisk and Liva Health Care, and is currently on a EIT Health research grant held jointly with Roche Diagnostics. JS has served on advisory boards for Janssen, Medtronic, Roche Diabetes Care, and Sanofi Diabetes; her research group (Australian Centre for Behavioural Research in Diabetes [ACBRD]) has received honoraria for this advisory board participation and has also received unrestricted educational grants and in-kind support from Abbott Diabetes Care, AstraZeneca, Medtronic, Roche Diabetes Care, and Sanofi Diabetes. JS has also received sponsorship to attend educational meetings from Medtronic, Roche Diabetes Care, and Sanofi Diabetes, and consultancy income or speaker fees from Abbott Diabetes Care, AstraZeneca, Medtronic, Roche Diabetes Care, and Sanofi Diabetes.

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Care, AstraZeneca, Medtronic, Novo Nordisk, Roche Diabetes Care, and Sanofi Diabetes. All other authors have no conflicts of interest to declare.

Novelty Statement

- Evidence-informed, acceptable, and accessible interventions are needed to reduce psychological barriers and support timely insulin uptake among adults with type 2 diabetes
- We piloted a novel, theoretically-grounded psycho-educational online intervention, compared to readily available online information about insulin among participants who were hypothetically unwilling to start insulin.
- The study design, a two-armed randomised controlled trial, is feasible and the intervention is acceptable, with high user ratings observed, and associated with reduced psychological barriers to insulin
- Findings support a fully-powered trial, with an optimised recruitment strategy, to establish the effectiveness, and further acceptability and implementation testing.

Acknowledgments

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Author contributions

EHT and JS conceived of, and EH project managed, the research program. EH, JS, TS and EHT led, and JF and VH contributed to the development of the website intervention. All authors contributed to study design. HH cleaned and analysed quantitative data and prepared tables. EHT and EH examined qualitative data. EHT prepared the first and subsequent drafts of this manuscript, following critical review by co-authors. All authors reviewed and approved submission of the final manuscript.

Structured Abstract

Aims: Acceptable and accessible interventions are needed to address ‘psychological insulin resistance’, which is a common barrier to insulin uptake among adults with type 2 diabetes. Our aim was to test the feasibility of a randomised controlled trial (RCT) study design and acceptability of a theoretically-grounded, psycho-educational, web-based resource to reduce negative insulin appraisals among adults with type 2 diabetes (T2D).

Methods: A double-blinded, parallel group, two-arm pilot RCT (1:1), comparing intervention with active control (existing online information about insulin). Eligible participants were Australian adults with T2D, taking oral diabetes medications. Exclusion criteria: prior use of injectable medicines; being ‘very willing’ to commence insulin. Primary outcomes: study feasibility (recruitment ease, protocol fulfilment, attrition, data completeness); secondary outcomes: intervention acceptability (intervention engagement, user feedback) and likely efficacy (negative Insulin Treatment Appraisal Scale (ITAS) scores at follow-up). Online surveys completed at baseline and two weeks.

Results: During 4-week recruitment, 76 people expressed interest: 51 eligible and 35 enrolled (intervention=17, control=18; Med[IQR] age= 62[53,69] years; 17 women). Protocol fulfilment achieved by 26 (74%) participants (n=13 per arm), with low participant attrition (n=6, 17%). Intervention acceptability was high (>80% endorsement, except format preference=60%). ITAS negative scores differed between-groups at follow-up (M diff=−6.5, 95%CI: -10.7 to -2.4), favouring the intervention.

Conclusions: This novel web-based resource (“Is insulin right for me?”) is acceptable and associated with a likely reduction in negative insulin appraisals, relative to existing resources. This pilot shows the study design is feasible and supports conduct of a fully-powered RCT.

Trial registration: ACTRN12619001382167

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Keywords: Psychological insulin resistance, intervention, type 2 diabetes, randomised control trial, attitudes

Introduction

Despite the changing landscape of treatments for type 2 diabetes, timely introduction of insulin therapy remains recommended for people with type 2 diabetes where HbA1c (average blood glucose over 8-12 weeks) is above target despite maximal oral or non-insulin injectable therapy.\textsuperscript{1,2} However, delay of clinically indicated insulin initiation is recognised internationally.\textsuperscript{3} Reasons for delays are multifaceted, including systemic barriers to the timely prescription of insulin and so-called ‘clinical inertia’ on the part of the health professional which can be compounded by ‘psychological insulin resistance’ (PIR).\textsuperscript{3-6} PIR is the reluctance of a person with type 2 diabetes to commence, use as recommended, or intensify insulin due to negative attitudes about insulin therapy.\textsuperscript{7} Longitudinal research has demonstrated an association between this reluctance and actual insulin uptake among those for whom insulin is clinically indicated.\textsuperscript{8} It has also been demonstrated that negative attitudes toward insulin are malleable.\textsuperscript{8,9}

While there is growing evidence for effective clinical strategies to support timely insulin initiation (e.g. a collaborative care approach, demonstration of injections),\textsuperscript{9-12} some healthcare professionals (HCPs) report a lack of confidence in providing insulin-specific counselling and raise concerns about the feasibility of implementing interventions to reduce PIR within routine care.\textsuperscript{4,13} There is also preliminary evidence for the effectiveness insulin-specific group education programs addressing psychological barriers to insulin.\textsuperscript{14-15} However, low uptake has been reported for clinician-delivered and group-education interventions to reduce PIR.\textsuperscript{13-15} Evidence informed, acceptable and accessible interventions to reduce PIR among adults with type 2 diabetes are needed, which may supplement clinical information and counselling.

Therefore, we developed ‘Is Insulin Right for Me?’, a theory-informed, web-based resource designed to reduce known psychological barriers to insulin therapy among adults with type 2 diabetes.\textsuperscript{16} Our program of research is guided by the UK Medical Research Council framework for developing and evaluating complex interventions (key elements: intervention development, assessment of feasibility and piloting, evaluation, and implementation).\textsuperscript{17} The systematic development of this intervention,
structured to acknowledge and address salient psychological barriers to insulin therapy, is detailed elsewhere. In the current study, we conducted a pilot randomised controlled trial (RCT) to examine feasibility of the study design, as well as the acceptability and likely efficacy of the intervention, relative to readily available online information about insulin therapy among Australian adults with type 2 diabetes. Findings will inform intervention and study design refinement, prior to conducting a fully-powered RCT.

Methods

A double-blinded, parallel group, two-arm pilot RCT (1:1 ratio) was conducted. The primary outcome was study feasibility, and secondary outcomes included acceptability and likely effect on attitudes to insulin. Baseline and two-week follow-up data collection was via online survey. Two-week follow up was chosen because a) it enabled participants reasonable time to view their allocated resource at their convenience, and b) impact of the resource on attitudes to insulin was anticipated to be, at least partially, immediate.

Ethics approval was granted by the Deakin University Human Research Ethics Committee (Project reference: 2019-253). This study was registered prospectively via the Australian and New Zealand Clinical Trials Registry (Trial Id: ACTRN12619001382167). Two departures from the registered protocol are reported: 1) the recruitment period was reduced (from eight to four weeks) due to a delay in commencement of recruitment while needing to maintain overall project timelines; 2) a research assistant involved in both participant interaction (i.e. sending resource allocation and survey access emails) and data collection procedures was aware of participants’ study arm allocation. However, participants and the wider investigator team (including statistician) remained blinded throughout data collection and analyses, and potential bias was minimised through the requirement for scripted interaction only (i.e. pre-drafted emails) which were recorded for future monitoring.

Participants and recruitment

Eligibility criteria were: adults 18 to 75 years; Australian resident; diagnosis of T2D; use of oral hypoglycaemic agents; read/write in English; access to an internet-enabled device for the duration of the study; no experience self-administering an injectable treatment for any illness or condition (including glucagon-like peptide-1 receptor agonist and insulin); and reporting at recruitment being ‘not at all’, ‘not very’, or only ‘moderately willing’ to initiate insulin therapy (i.e. excluding those already ‘very willing’ to start insulin). Clinical recommendation for insulin treatment was not a
criterion for eligibility. Eligibility criteria were assessed via self-reported responses to an online survey.

Study advertisements were placed on the researchers’ professional websites, e-newsletters and social media pages. National and state-based diabetes organisations and health professional networks were notified of, and encouraged to, promote the study. Study invitations (and a reminder 1 week later) were sent (via email) to a sample (n=502) of people with diabetes who had previously indicated consent to being contacted about research opportunities. Eligibility (e.g. age, place of residence, treatment type) of those invited was unknown. Participants who completed the follow-up survey had the opportunity to enter a prize draw to win one cinema or department store voucher of equal value (AUD $85).

Procedure

Participation was completely online. Potential participants were directed via a web-link to the study website (hosted by Qualtrics™) to access the Plain Language Statement and Consent Form. Following provision of informed consent, participants completed the eligibility screening questions and were immediately directed to the baseline survey; or to a message indicating ineligibility. Upon submission of the baseline survey, participants were considered ‘enrolled’ and were randomly allocated to the intervention or active control, and invited (via email), to access the relevant website within a two-week period. After one week, participants received a reminder email to access the resource. Following the two-week access period, participants received a link to the follow-up survey via email. Participants who had not completed the survey within one week of receipt were sent a reminder email. The study endpoint for all enrolled participants was marked by either submission of the follow-up survey (within 14 days), or attrition (non-submission at 15 days following survey request).

Intervention group

‘Is insulin right for me?’ is a novel web-based psychoeducational resource (Figure 1) developed using a systematic process grounded in behaviour change theory. The development of the resource is detailed elsewhere. Briefly, eight salient psychological barriers (i.e., determinants of behaviour) to insulin therapy were identified via literature search and mapped to eight relevant Theoretical Domains Framework (TDF) domains (knowledge; skills; social role and identity; beliefs about capabilities; beliefs about consequences; environmental context and resources; social influences; emotion). Relevant behaviour change techniques (BCTs) were identified for each barrier. The relevance of the identified barriers, TDF domains and BCTs were peer-reviewed by an external panel (n=4, experts in health psychology and behaviour change). Following consensus, the eight barriers

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were phrased as questions, for example: “Does insulin mean my diabetes is more serious?” Content responding to each psychological barrier was developed by the investigator team (experts in health psychology, primary care medicine and diabetes education) and refined following consumer feedback (cognitive debriefing interviews, n=6) and external expert peer review (n=5) to ensure relevance and clinical accuracy.

The intervention is purposefully brief and self-directed. The website home page asks participants which of eight questions about insulin are concerns for them. Content countering each barrier corresponds to one brief (200-500 words) webpage, including appropriate format of delivery (e.g. text, imagery, case studies, quizzes, videos). There was no expectation that participants should read all eight barriers or visit the website on multiple occasions. The intervention website also includes background information about the study and research team, brief information about the benefits of insulin, and a list of relevant freely available resources (including those made available to the control arm).

Control group
Control arm participants were directed to a static webpage including links to two publicly available text-based factsheets published by the National Diabetes Services Scheme (NDSS): “Insulin” and “Medication for type 2 diabetes”. The NDSS is an Australian Government initiative administered with assistance of Diabetes Australia. The control webpage also included links to further information about the study and research team (consistent with intervention).

Outcomes
The primary outcome was the feasibility of the two-armed RCT design. Indicators that the study design was not feasible included: failure to recruit, retain, or collect outcome data from the minimum sample (N=20, see Sample size) within the allocated recruitment period (two months). This was assessed via:

- Ease of enrolment/allocation: ability to recruit 40 consenting eligible participants in two months and the proportion of eligible participants who submit a baseline survey
- Protocol fulfilment: proportion of participants who accessed the allocated resource ≥1 time(s) measured via self-report (control) and website analytics (intervention)
- Attrition: Proportion of participants who do not submit a follow-up survey
- Data completeness: proportion of participants with complete baseline and follow-up survey data
Secondary outcomes were acceptability and likely efficacy of the novel web-based resource relative to the control. Acceptability was conceptualised as:

- Interaction with the intervention website recorded via Google analytics: number of resource visits; time (minutes) spent viewing the resource per person; most commonly viewed pages.
- User ratings (see Supplementary Table 1): frequency (%) of participants who agree with positively-worded study-specific items; themes identified from participants’ free-text responses (e.g. likes / dislikes about the resources, how it could be improved).

The likely effect of the intervention assessment outcome was mean change in Insulin Treatment Appraisal Scale (ITAS) Negative scores from baseline to two-week follow-up, compared to the control arm. Change in diabetes-specific knowledge (Michigan Diabetes Research and Training Center’s Revised Diabetes Knowledge Test: DKT-R) and hypothetical willingness to commence insulin therapy at follow-up were also assessed as secondary outcomes. Tertiary outcomes were change in diabetes distress (Problem Areas In Diabetes scale; PAID) and diabetes self-efficacy (Confidence in Diabetes Self-care scale; CIDS-2).

Data collection
Demographic, clinical, psychosocial, and study-specific acceptability data were collected by self-report (via online survey) at baseline and/or two-week follow-up (Supplementary Table 1). Website interaction data were collected post-intervention via WordPress, and for the intervention only Google analytics, and YouTube (video views).

Sample size
While no sample size calculation is required for pilot studies, a minimum sample of 20 participants (10 per arm) is recommended. We targeted 40 participants (20 per arm), allowing for an unknown, and potentially high, attrition rate (50%). The inflated sample was selected to ensure that a minimum sample size of N=20 was reached and inform expected attrition rates for a future definitive trial.

Randomisation
Enrolled participants were randomised to the intervention or control arm using randomly permuted block sizes of 2, 4 and 6, stratified by gender. The randomisation sequence was computer generated and the allocation fully concealed from the investigators, statistician and participants. Upon randomisation, participants received access details (via e-mail) to their allocated online resource.
study research assistant (not blinded) monitored incoming data and sent participants web resource and follow-up survey access and reminder emails.

Data analysis

Quantitative analyses were performed using Stata/SE 16.0 or IBM SPSS Version 25. Descriptive statistics were used to explore feasibility outcomes; participants’ baseline characteristics; psychosocial data at baseline and follow-up, as well as; resource acceptability ratings and website interaction data at follow up. Likely intervention effect was also explored predominantly using descriptive statistics of psychosocial data at baseline and follow-up. Additionally, as per the registered protocol, the mean difference in ITAS negative subscale and DKT-R scores between the intervention and control were examined using analysis of covariance (ANCOVA), adjusting for baseline scores. Complete cases were analysed regardless of intervention access.

Qualitative data generated by free-text responses to seven open-ended questions about the allocated resource were subjected to inductive template analysis (Supplementary Table 1). EHT and EH familiarised themselves with the data and generated an initial coding framework, iteratively revised following discussion with EH and JS, and applied by EHT. All authors reviewed the final theme (and subtheme) labels, descriptions, and illustrative quotes, and provided input into the presentation of these data.

Results

Assessment of feasibility

The number of participants assessed for eligibility during the recruitment period (30 October – 1 December 2019), enrolled (allocated), and retained at follow-up are summarised in Figure 2. Of those identified as eligible (n=51), 35 participants completed the baseline survey and were enrolled (intervention=17, control=18); that is 68% translation from eligibility to enrolment. The majority accessed their allocated website (intervention=15, 88%; control=13, 72%). Attrition at the 2-week follow-up survey was 17% (n=6) overall. Complete survey data were available for 97% (n=34/35) and 100% (n=29/29) of those who attempted the baseline and follow-up surveys respectively.

Sample characteristics

Participants’ characteristics are reported in Table 1. The intervention group were slightly older in age, self-reported a longer duration of diabetes and a greater number of diabetes-related complications. One third of participants recalled insulin having been discussed by their doctor (consistent across arms), with the last discussion occurring a median[IQR] of six [5,10.5] months

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prior to participation. None of the participants had been recommended insulin by their doctor previously.

Assessment of acceptability

At follow-up, the majority of the control group (n=13, 93%) self-reported resource access. The intervention was accessed a total of 25 times by 15 participants, the majority (n=10, 66%) accessing the intervention on one occasion (range=1-5). Median [IQR] time spent browsing the intervention, across sessions, was 13.3 [3.0,28.6] minutes. Eleven (73%) participants visited the ‘barrier’ webpages, for an average (range) of 1-2.5 minutes per webpage. Seven (46%) participants visited all eight barriers. Eight participants attempted ≥1 of the three embedded quizzes. A video demonstration of injecting insulin (32 seconds) generated five views (average content viewed = 13 seconds, 42%), and a video describing the progressive nature of type 2 diabetes (76 seconds) generated four views (full video viewed on each occasion). Participants’ ratings of the intervention and control resources are shown in Figures 3a and 3b, respectively. Both were rated positively by most participants (≥77%), though the intervention resource was rated slightly more positively across most domains. All participants allocated to intervention arm reported the resource as helpful and that it included the right amount of information (both n=13, 100%; compared with the control group: both n=9, 69%). However, five intervention group participants (38%) reported a preference to receive information about insulin in via hard copy resource (n=4) or from their health professional (n=1). Similarly, three (23%) of the control group participant reported a preference for hard copy resources.

Twelve intervention participants responded to one or more of the free-text acceptability questions (n=79 responses). One third of responses (n=29) indicated general satisfaction with the intervention and/or no comments for improvement. The remainder related to five overarching themes (Supplementary Table 2). Regarding ‘content acceptability’ (theme 1), the intervention was reported as “clear, concise and easy to understand”; informative and relevant; positive and supportive. However, some participants sought more specific clinical information (e.g. when insulin will be prescribed, dosage requirements). Participants reported the intervention increased their ‘understanding of and comfort with insulin’ (theme 2), with one participant stating it had helped them “get used to the idea that one day I may have to inject insulin”. However, some expressed ongoing concerns and “stigma attached to it [insulin]”. Some participants explicitly expressed an alternative ‘format preference’ (theme 3), while others proposed an extension of the current format to include accompanying hard copy materials, or links to a connecting support line. Suggestions for improved web resource ‘design and usability’ (theme 4) included improved print and search
functionality. Some participants reported that they would ‘recommend to others’ (theme 5), e.g. peers with diabetes, and suggested advertising it in diabetes-related community news/magazines.

Likely intervention efficacy
At two-week follow-up, there was a reduction compared to baseline, in negative insulin appraisals in the intervention arm, but not control arm, with a between-group mean difference of -6.5 (95% CI: -10.7 to -2.4) after adjusting for baseline appraisals (Table 2). There was little change in diabetes-specific knowledge compared to baseline (between-group mean difference of -2.4 (95% CI: -10.0 to 5.3), adjusted for baseline). There was minimal change in the proportion willing to commence insulin in either group (Table 3). Additionally, there was little change in self-efficacy for either arm, and some reduction in diabetes distress for the control arm only at follow-up compared to baseline (Table 2).

Discussion
This pilot study demonstrates the feasibility of a two-armed RCT, with online participation and data collection, to test the efficacy of a novel web-based intervention to reduce psychological barriers to insulin therapy. The sample achieved the minimum required (N=20) and was on track to exceed the target (N=40) had the recruitment period not been reduced. Protocol fulfilment was high, including web resource access, retention and data completeness, particularly given the low-intensity, low-contact nature of participation. However, there was considerable variation in participants’ interaction with the intervention website (e.g. viewing pages, watching videos, attempting quizzes), and both protocol fulfilment and retention was higher in the intervention arm relative to control arm. Importantly, there was preliminary evidence for the intervention’s acceptability and likely effectiveness (>0.5 standard deviation mean difference in negative insulin appraisals), with no indication of detrimental or beneficial effect on tertiary psychosocial outcomes. These findings justify the conduct of a fully powered RCT to determine effectiveness of the intervention, with consideration of refinements to both intervention and study design, as discussed below.

Pilot data suggest similar, if not greater, acceptability of ‘Is Insulin right for me?’ compared to existing publicly available relevant web-based resources. Though acceptability data is limited to those with full protocol engagement (which favours the intervention arm), and thus excludes those for whom the allocated resource may have been unacceptable. Furthermore, one third of eligible participants declined to take part prior to enrolment, suggesting potentially limited reach of the intervention. A minority of participants in the current study reported a preference to receive information in hard-copy and/or directly from health professionals (more so in the intervention

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group), and sought specific clinical information beyond the scope of the current intervention (e.g. medication interactions). Future research should investigate different delivery formats to meet the needs of the intended resource user. Intervention refinement could include improved web-page print functionality and consider provision of accompanying hard copy information. However, the current intervention cannot, and does not attempt to, replace effective health professional delivered insulin-specific education and counselling, but rather, if found to be effective, may be supplementary. Furthermore, while online health interventions offer potential for wide reach with minimal burden on healthcare resources, and have demonstrated favourable impact among adults with type 2 diabetes, there is no ‘one-size-fits-all’ solution to the complex problem of delayed medication uptake.

There are several study limitations. First, the study was, in effect, single-blinded only, with a member of the research team collecting outcome data also being involved in participant allocation. The sample recruited are not clinically indicated for insulin treatment. Participants reported within target HbA1c (on average); never having been recommended insulin by a health professional, and; were less resistant to (% ‘not at all willing’) insulin therapy than has been observed in an Australian primary care setting. Beliefs about diabetes are pervasive and may form long prior to insulin prescription, and as such, early intervention to counter unhelpful beliefs may improve receptiveness to medicating uptake downstream. Nonetheless, it is possible that those who have most to benefit were deterred by a study about insulin, as reported in prior studies testing PIR interventions. Due to the use of indirect recruitment methods, response rates and characteristics of non-responders cannot be determined, though it is likely that a relatively low response rate was achieved. Further, the small, self-selected sample, responding to a study with an advertised prize draw incentive, is not representative of the broader eligible population (e.g. more likely to report university-level qualifications and English as primary language relative to the general population, Australian Bureau of Statistics). Such limitations may be minimised through the future employment of a direct recruitment strategy via a national diabetes registry, targeting a stratified representative sample, and/or within a clinical setting, targeting those most at-need. Regardless, replication of the study in a larger, fully-blinded RCT is required and should employ similar conditions (i.e. online recruitment, prize draw), include collection of referral pathway data, and draw on the observed attrition rate and intervention effect in calculation of the target sample size.

Other limitations relate to selected outcome measures. Future studies should assess potential change in insulin-specific rather than general diabetes knowledge, which may contribute to attitude changes. Measurement of web-based resource(s) interaction differed between arms (intervention:
objective assessment; control: self-reported), potentially resulting in under or overestimated
resource interaction among the control group participants. Acceptability was assessed, in part, via
study-specific single items. While no acceptability criteria were pre-specified, indicators include the
fact that the intervention website was accessed by most intervention arm participants, who offered
high endorsement of positively-worded user ratings, and positive qualitative feedback. These data
support previous cognitive debriefing interviews which identified intervention content as useful and
engaging. Nonetheless, further qualitative exploration of intervention acceptability should seek to
recruit a more diverse sample and employ in-depth interviews, allowing for more detailed feedback
than captured here, and incorporate member-checking to assess validity of results.

These preliminary findings suggest ‘Is Insulin right me?’, a novel self-directed psycho-educational
web-based resource, may be acceptable to adults with non-insulin-treated T2D and associated with
a likely reduction in negative insulin appraisals relative to existing resources. Feasibility of study
design was confirmed, with high protocol fulfilment. Thus, a fully-powered RCT is warranted with
two-week follow-up, and consideration of longer follow-up, to determine the immediate and
sustained impact of the intervention on attitudes and receptiveness towards insulin. In addition,
future research is needed to examine the effectiveness of the intervention in terms of timely insulin
uptake among adults with T2D for whom treatment intensification is clinically indicated, as well as
real-world implementation outcomes.

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### Table 1 – Demographic, clinical characteristics and psychosocial outcomes at baseline, by treatment group

<table>
<thead>
<tr>
<th>Demographic and clinical characteristics</th>
<th>Intervention</th>
<th>Control</th>
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<td>Age (years)</td>
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<td>Language spoken at home: English</td>
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<td>Diabetes duration (years)</td>
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<td>Diabetes-related complications: ≥1</td>
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<td>5 (28)</td>
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<td>%</td>
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<tr>
<td>Mmol/mol</td>
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<td>52±12</td>
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<td>Current glucose-lowering medications:</td>
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<td>Metformin</td>
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</tr>
<tr>
<td>HCP discussion of insulin: yes</td>
<td>6 (35)</td>
<td>6 (33)</td>
</tr>
<tr>
<td>Insulin recommended previously: yes</td>
<td>0(0)</td>
<td>0(0)</td>
</tr>
</tbody>
</table>

Data are median [interquartile range], mean±SD, or n(%)

aCount of diabetes-related complications includes retinopathy, neuropathy, stroke, heart disease, kidney damage, vascular disease, sexual dysfunction.

bEight (23%) participants with missing data for Hba1c (Intervention: n=3, 18%; control: n=5, 28%)

HCP: healthcare professional
Table 2 – Psychosocial outcomes at baseline and follow up, by treatment arm and mean difference.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Time point</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>n</td>
<td>Mean±SD</td>
</tr>
<tr>
<td>Negative insulin appraisals (ITAS)</td>
<td>Baseline</td>
<td>17</td>
<td>55.7±8.0</td>
</tr>
<tr>
<td></td>
<td>2 weeks</td>
<td>15</td>
<td>46.9±9.0</td>
</tr>
<tr>
<td>Diabetes-specific knowledge (DKT-R)</td>
<td>Baseline</td>
<td>17</td>
<td>81.9±13.4</td>
</tr>
<tr>
<td></td>
<td>2 weeks</td>
<td>15</td>
<td>81.9±13.5</td>
</tr>
<tr>
<td>Diabetes distress (PAID)</td>
<td>Baseline</td>
<td>17</td>
<td>31.5±19.6</td>
</tr>
<tr>
<td></td>
<td>2 weeks</td>
<td>15</td>
<td>32.1±14.3</td>
</tr>
<tr>
<td>Diabetes self-efficacy (CIDS-2)</td>
<td>Baseline</td>
<td>17</td>
<td>84.3±9.5</td>
</tr>
<tr>
<td></td>
<td>2 weeks</td>
<td>15</td>
<td>85.8±7.1</td>
</tr>
</tbody>
</table>

CIDS-2: Confidence in Diabetes Self-care questionnaire for non-insulin-treated, range= 0-100; DKT-R: Michigan Diabetes Research and Training Center’s Revised Diabetes Knowledge Test, range= 0-100; PAID: Problem Areas in Diabetes, range: 0-100; ITAS: Insulin Treatment Appraisal Scale, Negative subscale range= 16-80. Higher scores indicate more of the concept assessed by the scale.

Table 3 – Hypothetical willingness to commence insulin at baseline and two-week follow-up, by trial arm allocation.

<table>
<thead>
<tr>
<th>Hypothetical willingness to begin insulin</th>
<th>Intervention</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=15</td>
<td>N=14</td>
</tr>
<tr>
<td></td>
<td>Baseline</td>
<td>2 weeks</td>
</tr>
<tr>
<td>Not at all willing</td>
<td>1 (7)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Not very willing</td>
<td>7 (47)</td>
<td>6 (40)</td>
</tr>
<tr>
<td>Moderately willing</td>
<td>7 (47)</td>
<td>8 (53)</td>
</tr>
<tr>
<td>Very willing</td>
<td>0 (0)</td>
<td>1 (7)</td>
</tr>
<tr>
<td></td>
<td>1 (7)</td>
<td>0 (0)</td>
</tr>
<tr>
<td></td>
<td>6 (43)</td>
<td>7 (50)</td>
</tr>
<tr>
<td></td>
<td>7 (50)</td>
<td>7 (50)</td>
</tr>
</tbody>
</table>

Figure 1

Screenshots of ‘Is insulin right for me?’ a web-based intervention
**Figure 2**
CONSORT flow diagram of pilot RCT recruitment, enrolment and retention rates

**Figure 3**
Participants' user ratings of the (a) intervention (n=13) and (b) control (n=13) resources.
Title: 'Is insulin right for me?': Feasibility of a pilot randomised controlled trial and acceptability of a web-based intervention to reduce psychological barriers to insulin therapy among adults with type 2 diabetes

Date: 2021-12-15


Persistent Link: http://hdl.handle.net/11343/299293