

# BMJ Open Web-based intervention to reduce psychological barriers to insulin therapy among adults with non-insulin-treated type 2 diabetes: study protocol for a two-armed randomised controlled trial of 'Is insulin right for me?'

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## ABSTRACT

**Introduction** Psychological barriers to insulin therapy are associated with the delay of clinically indicated treatment intensification for people with type 2 diabetes (T2D), yet few evidence-based interventions exist to address these barriers. We describe the protocol for a randomised controlled trial (RCT) examining the efficacy of a novel, theoretically grounded, psychoeducational, web-based resource designed to reduce psychological barriers to insulin among adults with non-insulin treated T2D: 'Is insulin right for me?'

**Methods and analysis** Double-blind, parallel group RCT. A target sample of N=392 participants (n=196/arm) will be randomised (1:1) to 'Is insulin right for me?' (intervention) or widely available online resources (control). Eligible participants include adults (18–75 years), residing in Australia, currently taking oral hypoglycaemic agents to manage T2D. They will be primarily recruited via invitations and reminders from the national diabetes registry (from a purposefully selected sample of N≥12 000). Exclusion criteria: experience of self-administered injectable; previously enrolled in pilot RCT; 'very willing' to start insulin as baseline. Outcomes will be assessed via online survey at 2 weeks and 6 months. Primary outcome between-group: difference in mean negative Insulin Treatment Appraisal Scores (ITAS negative) at 2-week and 6-month follow-up. Secondary outcomes: between-group differences in mean positive insulin appraisals (ITAS positive) and percentage difference in intention to commence insulin at follow-up time points. All data analyses will be conducted according to the intention-to-treat principle.

**Ethics and dissemination** Deakin University Human Research Ethics Committee (2020–073). Dissemination via peer-reviewed journals, conferences and a plain-language summary.

**Trial registration number** ACTRN12621000191897; Australian and New Zealand Clinical Trials Registry.

## INTRODUCTION

Type 2 diabetes (T2D) is a progressive condition that requires timely adjustment of treatment to achieve and maintain optimal glucose outcomes<sup>1–3</sup> and prevent or delay the onset of

## Strengths and limitations of this study

- 'Is insulin right for me?' is the first self-directed, theoretically grounded web-based intervention targeting salient psychological barriers to insulin.
- This fully powered randomised controlled trial will provide evidence of the impact of 'Is insulin right for me?' to reduce negative insulin appraisals and increase intention to initiate insulin among adults with non-insulin-treated type 2 diabetes recruited via a national diabetes registry.
- Comprehensive data collection, including demographic and clinical characteristics, psychosocial outcomes and website analytics, will enable process evaluation analyses.
- Limitations include the self-selected sample, which may lead to an under-representation of those hardest to reach or most at need (ie, those not at all willing to commence insulin).
- Furthermore, this study is not designed to identify the intervention's impact on actual timely insulin uptake nor feasibility of implementation within clinical care.

micro and macrovascular complications.<sup>4,5</sup> A staged approach to pharmacological management of glucose in T2D is recommended,<sup>1–3</sup> including early consideration and initiation of insulin where glycaemic outcomes are above target (typically haemoglobin A1c (HbA1c) >7%, 53 mmol/mol<sup>3</sup>) despite maximal dose of non-insulin medicines. However, vast literature suggests that treatment adjustment, including insulin initiation, is often delayed well beyond the point of clinical need.<sup>6,7</sup> For example, a large-scale (N≥80 000), retrospective study conducted in the UK, identified HbA1c at insulin initiation for people with T2D was ≥8.7% (72 mmol/mol) with a



median time until insulin initiation of  $\geq 6$  years.<sup>8</sup> Finally, a recent Australian primary care-based prospective study identified that, among adults with T2D for whom insulin was clinically indicated (HbA1c  $\geq 7.5\%$ /58 mmol/mol, with maximal oral therapy), receiving usual care, only 31% had initiated insulin within 24 months.<sup>9 10</sup>

Reasons for the delay of treatment intensification are multifaceted,<sup>7 11 12</sup> and effective interventions targeting barriers to insulin use are required.<sup>13–15</sup> At a systemic or health professional level, promising results have been shown using multidisciplinary models of care (eg, an enhanced practice nurse role within primary care setting<sup>9</sup>), effective consultation strategies (eg, collaborative approach to care<sup>16</sup>) and insulin-specific structured education programmes.<sup>17 18</sup> However, there is a parallel need for interventions, which directly target the psychological barriers (negative beliefs and attitudes) to insulin held by the person with T2D. Our prior research demonstrated, independent of an optimised model of primary care ('stepping up'), attitudes towards insulin were associated with hypothetical willingness to initiate insulin, which, in turn, predicted actual insulin use 12 months later.<sup>14 19</sup> Elsewhere, qualitative research with people with T2D attending an insulin-specific education programme identified an unmet need for psychological barriers to insulin to be addressed appropriately.<sup>20</sup> Furthermore, unaddressed negative insulin appraisals may have long-lasting impact on the optimal use of insulin and/or emotional well-being following insulin initiation.<sup>21–23</sup> Such psychological barriers to insulin use include, for example, worries about performing injections, potential pain and side effects as well as feelings of guilt and self-blame about the onset of the condition and/or the need for treatment progression.<sup>24</sup>

Few evidence-based interventions targeting psychological barriers to insulin have been developed and fewer still are evaluated adequately, or implemented beyond research studies.<sup>17 25 26</sup> Furthermore, preliminary data from relevant clinic-based and insulin starts group-education interventions suggest low intervention uptake among people with T2D.<sup>17 26</sup> In addition to common barriers to outpatient clinic and structured education programme attendance discussed elsewhere,<sup>27 28</sup> this low uptake may be in part due to individuals concern that participation would lead to insulin acceptance.<sup>26</sup> Furthermore, health professionals report limited time and resources to facilitate insulin starts,<sup>12</sup> and express concerns about the added burden of intervention delivery on their already limited time.<sup>26</sup> Effective interventions that complement clinical care (but are not reliant on a health professional for delivery) have the potential to be acceptable to both people with T2D and their health professionals.

Given the sheer size of the population with T2D, the potential for scalable implementation is also an important consideration. The internet may be an ideal platform to reach those with T2D with concerns about insulin, as it also allows for anonymity in information seeking. One-third of Australian adults with T2D and suboptimal HbA1c report

seeking online health information in a past 12 periods.<sup>29</sup> Furthermore, online interventions for the management of T2D with clear theoretical groundings and based on behaviour change techniques (BCTs) show favourable outcomes.<sup>30</sup> While peak health bodies publish resources online about T2D treatments, these materials are not typically theoretically informed, do not use evidence-based BCTs<sup>31 32</sup> and are rarely developed in consultation with, or evaluated among, people with T2D. Furthermore, these resources are rarely targeted at addressing salient psychological barriers to treatment use.

In line with UK Medical Research Council guidance for developing and evaluating complex intervention, we developed a theoretically grounded, psychoeducational, web-based resource for people with non-insulin-treated T2D designed to reduce salient psychological barriers to insulin therapy: '*Is insulin right for me?*'.<sup>33</sup> A pilot study demonstrated feasibility of a two-arm randomised controlled trial (RCT) design to test intervention efficacy, compared with widely available online informational resources as well as acceptability of the intervention among adults with T2D.<sup>34</sup>

This protocol describes the design of a double-blinded, parallel group, individually RCT (two-arms, 1:1 ratio), comparing '*Is insulin right for me?*' (intervention) with widely available online text-based resources about insulin (control) among adults with non-insulin-treated T2D. We hypothesise an immediate (2 weeks) and sustained (6 months) positive effect of the intervention, compared with control, on negative insulin appraisals. We also expect the intervention to be acceptable to users and to be associated with immediate and sustained improvement in positive insulin appraisals and hypothetical willingness to begin insulin therapy.

## METHODS AND ANALYSIS

### Study setting

Participation in this Australian study, including provision of informed content, data collection and intervention exposure, is completely online, using personal computers/mobile devices.

### Participants and recruitment

Potential participants will be enrolled in the study only if they meet all the inclusion criteria and none of the exclusion criteria. Inclusion criteria: aged 18 to 75 years; diagnosed with T2D; use of oral hypoglycaemic agents; able to read/write in English and capable of providing informed consent; residing in Australia; access to an internet-enabled computer or tablet device for the duration of the study. Exclusion criteria: diagnoses of diabetes other than T2D; current or prior experience of self-administered injectable treatment for any illness or condition (including diabetes); unable to read/write in English; unable to use/access internet-enabled devices; enrolled as a participant in the pilot RCT<sup>34</sup>; reports being 'very willing' to initiate insulin therapy (measured using

a single-item 'hypothetical willingness' questionnaire<sup>35</sup>), that is, rendering it impossible to record improvement in this outcome measure.

The primary method of recruitment will be via invitation from the National Diabetes Services Scheme (NDSS). A random sample of  $\geq 12\,000$  NDSS registrants, aged 18–75 years with non-insulin-treated T2D, who have previously consented to being contacted about research opportunities, will be invited to take part either via email (n=10 000) or postal mail (n=2000) as per the registrants preferred method of contact. The NDSS is an Australian government initiative, administered by Diabetes Australia. The NDSS registry includes over 1.2 million Australians with T2D and is considered to be one of the most comprehensive and up-to-date diabetes prevalence data sets in Australians.<sup>36</sup> The random sample will be stratified by state and territory to facilitate representation across Australia, ideally in line with population distribution across the eight states and territories. The research team will not have access to NDSS registrants' details unless they make contact/take part in the study, and the NDSS will not be notified of participating registrants. The total number of invited registrants was selected based on adoption of a conservative response rate of 8%,<sup>37</sup> and an expected 46% translation from consent to enrolled participant (as seen in the pilot RCT<sup>34</sup>). Invited NDSS registrants will receive an invitation reminder via e-mail or postal mail 2 weeks following first contact. If our target sample size is not reached within 4 weeks of the initial invitation, a second NDSS e-mail/mailout will be sent until our target sample size is reached or the 2-month recruitment period has concluded. The number of registrants contacted and method (e-mail vs mail) for subsequent recruitment efforts will be informed by the success rate from the original invitation (ie, percentage enrolled reporting hearing about the study via email or mail invitation). The study will also be advertised online via the researchers' affiliated professional websites and social media accounts, and a study flyer will be circulated to diabetes researcher and health professional networks.

### Study procedure

The schedule of enrolment, intervention and assessment is detailed in Figure 1. Study recruitment will be open for a maximum of 2 months or until sample size (enrolled) is reached. Participation (from study entry to exit) will be for a duration of 6 months. Study advertisements will direct potential participants to the study website (hosted by Qualtrics) to access the Plain Language Statement, provide informed consent and complete screening questions online. Eligibility will be determined automatically based on responses. Eligible participants will be directed immediately to complete an online baseline survey, and, following submission, will be allocated at random to one of two study arms. Randomised participants will receive an email including details about how to access the relevant online resources for their study arm. For participants allocated to the intervention group, this will include a unique

username and password enabling access. All participants will be asked to access their allocated resource(s) at their convenience within the following 2-week period, with no further instruction provided regarding the number of resource visits or length of time viewing the resources(s). One week following allocation, participants will receive a reminder email to access/log into the resource. Participants will be sent an email with a link to the online follow-up survey at 2 weeks and 6 months following baseline. The 2-week follow-up survey will be available for completion for 2 weeks, and the 6-month follow-up survey will be available for completion for 3 weeks. Study end point for all participants will be marked by either submission of the 6-month follow-up survey (within 21 days of request) or non-submission at 22 days following the survey request.

### Randomisation and blinding

After baseline survey submission, participants will be stratified by gender (due to prior gender imbalance observed among participants recruited to related studies<sup>9 21</sup>) and randomised to either the intervention or control arm using computer-generated, randomly permuted block sizes of four, six or eight. The randomisation sequence will be computer generated and the allocation will be fully concealed from both the investigators and participants. On randomisation, participants will receive an email from a researcher, independent of the study investigator team and who does not have access to the incoming survey data (except for participant ID, name, gender and email address), specifying access details to their allocated online resource. The statistician, participants and investigator team will remain blinded to study arm allocation throughout data collection and analyses. The project manager (EEH), who will monitor incoming survey data, will be blinded from study arm allocation except where a participant self-identifies study arm allocation within the follow-up surveys (eg, in a free-text response box). Any breaches will be recorded and reported with the main findings.

### Intervention

Intervention group participants will receive access to a novel psychoeducational web-based resource, '*Is insulin right for me?*'. The intervention was developed using a systematic process grounded in behaviour change theory and has been described elsewhere.<sup>33</sup> In brief, eight salient psychological barriers to insulin therapy were identified via literature search. Each barrier (ie, determinant of behaviour) was mapped to relevant domains of the theoretical domains framework.<sup>38</sup> Determinants were then mapped onto BCTs considered relevant to overcoming the modifiable barriers.<sup>32 38</sup> Content responding to each 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 for people with T2D and clinical accuracy.

The eight barriers targeted in the ‘*Is insulin right for me?*’ resource are phrased as common questions, with one barrier/question per website page (see [table 1](#)). The resource home page lists all eight barriers/questions as well as a preview (a key summary statement that responds to the question and content overview). The intervention is purposefully brief and self-directed, with the home page text asking which of eight questions about insulin are concerns for participants. For each selected barrier, an active intervention is presented on a separate webpage (200–500 words; 5min read) to facilitate user engagement. In addition, the resource includes information about the key benefits of insulin therapy<sup>1</sup>: that it lowers blood glucose levels<sup>2</sup>; can lower your risk of long-term health complications<sup>3</sup>; can make you feel better and<sup>4</sup> can make managing your diabetes more flexible. The lesser focus on benefits than barriers is due to the evidence that most people with T2D experience/report barriers to insulin therapy despite endorsing benefits.<sup>14 19</sup> Finally, the resource also provides links to other resources about T2D and insulin available from the NDSS and study information.

### Control group

Control arm participants will be directed to a static webpage including links to publicly available text-based NDSS factsheets, including: ‘Insulin’ and ‘Medication for type 2 diabetes’. The control group webpage also includes links to further information about the study and research team (consistent with intervention arm).

### Outcomes

The coprimary outcome measures are the difference in mean negative insulin appraisals, as measured by the Insulin Treatment Appraisal Scale (ITAS) Negative subscale score,<sup>39</sup> between the intervention and control arm at 2-week and 6-month follow-up, adjusted by baseline scores. We hypothesise that, at 2 weeks, a statistically significant difference in mean ITAS negative scores of  $\geq 4$  points (approximately 0.5 SD) will be observed between the intervention and control arm, favouring the intervention arm; and that this difference will be sustained at 6 months.

Our secondary outcome measures are immediate and sustained between-arm differences in: (a) positive insulin appraisals, as measured by ITAS positive subscale score<sup>39</sup>; and (b) hypothetical willingness to begin insulin therapy, as measured by a single item.<sup>35</sup> We hypothesise that, at 2 weeks and 6 months, a statistically significant between-group difference will be observed in:

1. mean ITAS positive scores, adjusted for baseline scores, favouring the intervention arm.
2. The percentage of participants who respond ‘not at all willing’ (hypothetical willingness item). The intervention arm will be less likely to be ‘not at all willing’ compared with controls.

The following survey data will be examined by study arm for process evaluation purposes:

1. Clinical discussion and recommendation of insulin therapy, change in medications and satisfaction with diabetes management at 6-month follow-up
2. Change in secondary psychosocial outcome scores at 2-week and 6-month follow-up: diabetes-specific distress (PAID),<sup>40</sup> illness perceptions (BIPQ),<sup>41</sup> diabetes-specific self-efficacy (CIDS),<sup>42</sup> study-specific insulin-related knowledge questionnaire.
3. Diabetes-specific knowledge at baseline.<sup>43</sup>
4. Study-specific resource use and acceptability (study specific items) as 2-week follow-up.

[Figure 1](#) details the self-reported demographic, clinical, psychosocial and study-specific data to be collected and the time points at which they are to be collected. In addition, website analytics data will be collected to assess protocol fulfilment with the intervention resource (ie, proportion of ‘enrolled’ participants who accessed the ‘*Is insulin right for me?*’ website at least once). Various analytics (eg, average number of online resource visits; time (minutes) spent on online resource; most commonly (frequency, %) viewed pages) will be examined to explore any relationship(s) between type/duration of content accessed and the study outcomes. Finally, number of views and average time spent watching two videos embedded in the intervention resource will be captured via YouTube.

### Sample size

Using a power analysis for repeated measures analysis of variance, a minimum sample size of N=250 (n=125 per arm) is required to detect a minimally important difference of half a standard deviation (SD=9) in ITAS Negative Scores<sup>39</sup> between study arms with a correlation of 0.65 between repeated measures, at 85% power and 0.05 significance level using a two-sided test. Assuming a 20% attrition rate at 2 weeks<sup>34</sup> and a further 20% attrition at 6 months, the targeted sample size inflates to approximately N=392 (n=196 per arm). Overall, a 40% attrition rate is incorporated into our estimated sample size and replacements will not be made for losses to follow-up.

### Data collection, management and analysis

Participant-reported data will be collected online via Qualtrics, hosted through the Deakin University secure network. Consent, eligibility screening and baseline survey data will be collected in a single sitting (directed via study advertisement link) and an email will provide enrolled participants with a link to online follow-up surveys. The intervention website will require participant log-in, allowing for automatic collection of website usage data for each intervention participant via Google Analytics.

To improve participant retention and protocol compliance, trial participants will receive reminder emails to access/view the allocated online resource (sent to all participants 2 weeks following allocation. In addition, reminder emails will be sent at 1 week (and 2 weeks

**Table 1** Description of the eight barriers targeted in the ‘*insulin right for me?*’ resource

Barrier (question)	Resource aim (using behaviour change theory)	Format of delivery
Does insulin mean my diabetes is more serious?	<ul style="list-style-type: none"> <li>▶ Challenge beliefs: insulin therapy can be clinically recommended at any time</li> <li>▶ Shape knowledge: provide information about the role of insulin</li> <li>▶ Motivate: diabetes is always serious</li> </ul>	Interactive quiz; video depicting progressive nature of T2D (imagery and text), imagery and personal quote
Do insulin injections cause complications?	<ul style="list-style-type: none"> <li>▶ Shape knowledge: provide information about diabetes complications risk factors</li> <li>▶ Motivate: acknowledge where this belief comes from. Validate concerns</li> </ul>	Text; imagery and personal quote
Is it my fault I need to inject insulin?	<ul style="list-style-type: none"> <li>▶ Identification of self as role model: ‘you are doing this for yourself, insulin is a good thing’</li> <li>▶ Restructuring the social environment: being prepared for how others may react</li> <li>▶ Encouragement and support: sharing how you feel with others</li> </ul>	Text; case study (with audio recording); statistic and personal quote
Will I gain weight?	<ul style="list-style-type: none"> <li>▶ Shaping knowledge: many people gain a small amount of weight when they commence insulin therapy. There are things that you can do to prevent unhealthy weight gain</li> <li>▶ Motivate: acknowledge and validate fear</li> <li>▶ Saliency of side effect: for many, weight gain is small</li> </ul>	Interactive quiz; text; imagery and personal quote
Will injecting hurt?	<ul style="list-style-type: none"> <li>▶ Shaping beliefs: dispel myths</li> <li>▶ Manage expectations: information and strategies to alleviate and minimise discomfort</li> <li>▶ Demonstration: of a person injecting insulin</li> <li>▶ Encouragement: to discuss insulin therapy and any concerns with a health professional</li> <li>▶ Imagery: small/fine needles and site of the injection</li> </ul>	Text; demonstration of injecting insulin; imagery and personal quote
What about hypos?	<ul style="list-style-type: none"> <li>▶ Shape knowledge: frequency/severity of hypos</li> <li>▶ Motivate: acknowledge/validate fears ‘having concerns about hypos is natural’.</li> <li>▶ Reduce emotional valence of the fear: low risk of having a severe hypo. Support is available</li> </ul>	Interactive quiz; text; imagery and personal quote
Will injecting insulin be a burden?	<ul style="list-style-type: none"> <li>▶ Increase knowledge: you can take insulin with you wherever you go</li> <li>▶ Increase self-efficacy: the changes you need to make are minimal and you can handle them.</li> <li>▶ Weigh pros vs cons: insulin can make management of diabetes easier</li> </ul>	Text and personal quote

Continued



Table 1 Continued

Barrier (question)	Resource aim (using behaviour change theory)	Format of delivery
What will others think of me?	<ul style="list-style-type: none"> <li>▶ Identification of self as role model: 'you are doing this for yourself, insulin is a good thing'</li> <li>▶ Restructuring the social environment: being prepared for how others may react</li> <li>▶ Encouragement and support: start a 'safe' conversation to share how you feel with others</li> </ul>	Case studies with examples (with audio recording); text; and personal quote

T2D, type 2 diabetes.

for 6-month time-oint) to participants who have yet to commence their online follow-up surveys. To aid recruitment and retention, participants who complete all three surveys (the baseline, 2-week and 6-month follow-ups) will be entered into a prize draw to win one of 20 AUD\$100 e-gift vouchers.

Participants who do not access their allocated resource(s) will still be followed up until the end of the trial unless they withdraw from the trial. Participants who do not complete the 2-week follow-up survey will have 'missing data' at 2 weeks, but remain eligible to complete

the 6-month follow-up survey. Participants who do not complete the 6-month follow-up survey within 3 weeks of receipt will have 'missing data' at 6 months. Participants with missing data at both follow-up time points will be deemed 'lost to follow-up'.

Study data collected from withdrawn participants will be deleted, with the exception of basic deidentified sample characteristics (gender, age, diabetes duration), trial arm allocation, timing of withdrawal and reason for withdrawal, where applicable.

TIMEPOINT		STUDY PERIOD			
		Enrolment	Post-allocation		
		Screening	Baseline	Two weeks	Six months
<b>ENROLMENT:</b>					
Informed consent		X			
Eligibility screen		X			
Randomisation			X		
<b>INTERVENTIONS:</b>					
Intervention: Is insulin right for me?				→	
Control				→	
<b>ASSESSMENTS:</b>					
Contact information	Name <sup>a</sup> , email address <sup>a</sup>	X		X	X
Pilot	Participation in the pilot study: yes/no <sup>a</sup>	X			
Recruitment	Referral method (e.g. NDSS invite)	X			
Demographics	Age <sup>a</sup> , gender <sup>a</sup> , country of residence <sup>a</sup>	X			
Diabetes	Birth country, language, relationship status, employment, qualifications, postcode		X		
	Diabetes type <sup>a</sup> , duration <sup>a</sup> , and management regimen <sup>a</sup> , prior use of injections <sup>a</sup>	X			
	Diabetes medications, most recent HbA1c, glucose monitoring behaviour		X		X
General health	Diabetes-related co-morbidities <sup>b</sup> , weight, height		X		
Clinical discussion of insulin therapy	Recall of prior clinical discussion and recommendation of insulin		X		X
Previous information about insulin therapy	What information about insulin have you read		X		
Psychological insulin receptiveness	Hypothetical willingness to commence insulin (35) <sup>a</sup>	X		X	X
Attitudes towards insulin	Insulin Treatment Appraisal Scale: ITAS (39)		X	X	X
Knowledge	Diabetes-specific: Diabetes Knowledge Test-True/False Version: DKT (43)		X		
	Insulin-specific knowledge: Study specific items		X	X	X
Diabetes-specific distress	Problem Areas In Diabetes: PAID (40)		X	X	X
Illness perceptions	Brief Illness Perceptions Questionnaire: BIPQ (41)		X	X	X
Diabetes-specific self-efficacy	Confidence In (type 2) Diabetes Self-management scale: CIDS-2 (or insulin version at follow-up for participants commenced insulin (CIDS-1) (42)		X	X	X
Diabetes management satisfaction	Study specific item		X	X	X
Resource use and acceptability	Resource access (yes/no). Reasons for not accessing; OR user rating scale (were questions answered?), free-text feedback (questions, likes/dislikes, improvements)			X	
Further comments	Free-text box for participant to provide further feedback.			X	X

**Figure 1.** Schedule of enrolment, interventions, and assessments. a—Compulsory questions for participation. b—Co-morbidities included: kidney disease, retinopathy, neuropathy, heart disease, stroke, vascular disease, sexual dysfunction, other (to be specified). HbA1c, haemoglobin A1C; NDSS; National Diabetes Services Scheme.

## Data storage

At study conclusion, survey data and website usage data (for intervention participants only) will be downloaded from Qualtrics and Google Analytics, respectively, and linked according to participant ID. Identifiable information (email, name) will be separated from study data and stored along with participant ID number in a password-encrypted excel spreadsheet. All data will be stored in a secure electronic file accessible only by the research team. In accordance with clinical trial regulations, data will be kept for a minimum of 15 years after study completion and then disposed by erasing of electronic files.

## Statistical methods

Quantitative data analyses will be performed using Stata/SE V.16.0 and/or IBM SPSS V.26. Descriptive statistics will be used to describe participant baseline characteristics and psychological outcomes at each time point. Participant characteristics at baseline will be visually assessed by allocation for imbalance. The overall characteristics of the study cohort will be compared with those lost to follow-up.

An intention-to-treat approach will be adopted, whereby participants will be analysed according to the arm they were allocated to, and all participants will be included in the analysis. A linear mixed effects model will be used to estimate the difference in mean ITAS negative scores between arms at 2 weeks and 6 months using restricted maximum likelihood estimation. Treatment arm, all three time points (baseline, 2 weeks and 6 months), and the interaction between treatment arm and time points will be included as fixed effects in the model. Random effects will be used to account for repeated participant measures. The outcome measure will be adjusted by age, diabetes duration and education should these be imbalanced between the arms at baseline. As a sensitivity analysis, pattern mixture models will be used to determine whether study conclusions from the analyses described above would change should data be missing not at random.

ITAS positive scores (secondary outcome) and continuous psychosocial process evaluation outcomes (eg, PAID, BIPQ, CIDS) will be analysed using the same modelling approached described above. An ordinal logistic mixed effects model will be used to quantify between-arm differences in the willingness to begin insulin therapy (secondary outcome) at various time points.

Descriptive data will be used to explore trends in protocol fulfilment, website analytics and acceptability data as well as medication changes and clinical discussion of insulin therapy at 6 months separately for each study arm.

## Monitoring

Coauthors EH-T and JS are the responsible investigators and will oversee the research project. During recruitment and data collection, the number of potential participants consenting, eligible and enrolled as well as dates

of all participant encounters (ie, enrolment; intervention access & reminder emails; survey access, reminder and closure) and survey completion will be monitored by EEH and communicated to investigator team. The primary funding body will be allowed access to all deidentified data from the study for audit purposes, if requested.

This research protocol does not include administration or manipulation of, or investigation of the effects of, any pharmacological or therapeutic goods. However, in line with the pharmacovigilance reporting requirements of the funding body, all survey data collected will be screened for adverse events that may be associated with the funding body's products and, in the event of the research team becoming aware of a potential adverse event, participants will be contacted (via email) and invited to respond to additional questions about this event (eg, medication brand name, dose and timing, healthcare utilisation symptoms, other consequences). Non-response will not affect participation in the study proper. Deidentified information obtained about the event will be submitted to the funder and, if relevant, the Australian Therapeutic Goods Administration.

## Patient and public involvement

People with T2D were involved in the review and iterative refinement of the intervention content and design. This involved cognitive debriefing interviews with six adults with T2D to review draft content during intervention development, for which the findings and consequential refinements are detailed elsewhere.<sup>33,34</sup> In addition, user ratings and qualitative feedback were provided by 13 pilot RCT participants who were allocated to the intervention.<sup>34</sup> Refinements made to the intervention following piloting included, for example, improving website navigation between barrier webpages and the addition of 'print-friendly' downloadable Portable Document Format (PDF) content.<sup>34</sup> People with T2D were not involved in the development of the study design, nor will they be involved in conduct of the study or dissemination of the study findings.

## Ethics and dissemination

This trial received ethical approval Deakin University Human Research Ethics Committee (Ref: 2020-073). This study will be conducted in compliance with this protocol (V.SA-2017-11697; V2.2e 16 June 2020), which is registered with the Australian New Zealand Clinical Trials Registry (ACTRN: 12621000191897, registered 23 February 2021). Note, this protocol was submitted for registration on 10 December 2020, prior to recruitment commencement (11 January 2021), though approved retrospectively following enrolment of the first participant and prior to last participant enrolment. Any changes to the protocol will be communicated to the human research ethics committee, funder and trial register. Protocol registration will be updated with any approved amendments to the protocol, and protocol departures will be documented in any reports or manuscripts resulting from this study.

Potential participants view the study plain language form online (online supplemental file 1) and must indicate consent (by ticking a box) prior to participating. Participants

are free to withdraw from the study at any time, and for any reason, prior to completion of data collection.

The findings will be prepared for academic presentation at scientific meetings and in peer-reviewed journals. A lay summary of findings will be published on the research team's website and disseminated via e-newsletter. Study findings will also be reported to the funding body.

Deidentified data may be made available, on request, to the funding body.

## DISCUSSION

This RCT will provide high-quality evidence regarding the efficacy and acceptability of a novel, web-based resource: *'Is insulin right for me?'*. Using best-practice intervention development principles and evaluation guidance,<sup>33 34</sup> the intervention was designed to reduce salient psychological barriers to insulin, which are extremely common among people with T2D and associated with deleterious delay of insulin uptake.<sup>14 44</sup> To our knowledge, this study will be the first fully powered RCT conducted to test the impact of any intervention specifically designed to address salient psychological barriers to insulin among adults with T2D, reporting some level of psychological insulin resistance.

The described study will provide evidence of the acceptability of this web-based resource among Australians with T2D, who report some level of psychological insulin resistance, which may inform real-world implementation strategies and further refinements as required. A potential limitation of this trial is the expected low response rate and self-selection bias of the sample recruited via an invitation from the NDSS, which may not be representative of those most in need (ie, those with a high HbA1c yet not at all willing to commence insulin) as well as linguistically diverse communities. Participants' demographic characteristics (eg, gender, state/territory, language, country of birth) will be compared with the general Australian population of adults with T2D to examine the representativeness of the sample. If the intervention is shown to be efficacious, further research will be warranted to investigate its impact on timely insulin uptake (and consequently on HbA1c) as well as the feasibility of implementation in primary care settings among adults with T2D for whom treatment intensification is clinically indicated.

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**Contributors** EH-T and JS conceived of the intervention and the described program of research. EH-T and JS developed the study protocol, with input from EEH, HHM, JF, VH and TS. EEH, JS, TS and EH-T led the development of the intervention, with contributions from JF, and VH. HHM calculated the sample size and developed the statistical analysis plan. EH-T was responsible for drafting the manuscript, which EEH, HHM, JF, VH, TS and JS reviewed and contributed to. All authors approved the final manuscript.

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## Supplementary File 1. Plain Language Statement and Consent Form

### Attitudes towards insulin therapy for people with type 2 diabetes

Plain Language Statement and Consent Form
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**Date:** May 2020

**Full Project Title:** Development, Feasibility, and Efficacy of a Web-Based Intervention to Reduce Psychological Barriers to Insulin Therapy among Adults with Type 2 Diabetes (Stage 3: Full RCT)

**Principal Investigators:** Dr Elizabeth Holmes-Truscott and Professor Jane Speight, The Australian Centre for Behavioural Research in Diabetes (ACBRD), Deakin University

**Associate Investigators:** Dr Edith Holloway, ACBRD, Deakin University; Professor Timothy Skinner, Department of Rural Health, La Trobe University; Associate Professor John Furler, Department of General Practice, The University of Melbourne; Professor David O'Neal, St Vincent's Hospital, The University of Melbourne; and Dr Virginia Hagger, School of Nursing and Midwifery, Deakin University.

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Dear participant,

You are invited to take part in this research project because you have type 2 diabetes, are aged between 18 and 75 years of age and take oral medication to manage your diabetes. In this study, we are investigating people's attitudes towards injecting insulin. We are also testing online resources about medications for type 2 diabetes. We want to know which resource(s) is the most useful for people with type 2 diabetes, who have questions or concerns about injecting insulin. Taking part involves exploring the web-based resource(s) and completing three online surveys over 6 months.

Below you can read further information about the study, so that you can decide if you would like to take part. Please take the time to read this information carefully. You can also print a copy of the [PDF](#) (*hyperlink to ethics approved version of the PLS inserted here*) or ask the study team for a hard copy to be sent to you. Ask the study team questions about anything you don't understand or want to know more about.

If you consent to taking part in this study, please click the box at the end of this webpage.

#### What is the purpose of this research?

Insulin is very effective for lowering blood glucose levels. Your doctor may recommend injecting insulin if other medications are unable to keep your blood glucose within your target range. However, people with type 2 diabetes may have concerns or questions about starting insulin. The purpose of this study is to test whether web-based resource(s) are useful for people with type 2 diabetes who have questions or concerns about starting insulin injections. The findings of this research may be used to inform what online resources about medications are available for people with type 2 diabetes in the future. We expect a total of 392 adults with type 2 diabetes will take part in this study.

### Who can take part?

You can take part in this study if you:

- have type 2 diabetes and are currently taking oral medication to manage your diabetes. If you are currently, or have in the past, used self-administered injectable treatment for any illness or condition (for example insulin) you are NOT eligible to take part in the study.
- are between 18 and 75 years of age
- are able to read and speak English
- currently live in Australia
- have access to the internet and a computer (desktop, laptop) or tablet

You are not eligible to take part if you participated in the associated Pilot Study (between October and December 2019): Development, Feasibility, and Efficacy of a Web-Based Intervention to Reduce Psychological Barriers to Insulin Therapy among Adults with Type 2 Diabetes (Stage 2: Pilot Study).

### What does taking part involve?

Taking part in this study will involve:

- Accessing and viewing a web-based resource(s) about medications for type 2 diabetes. You will be asked to do this at least once (and as many times you like) over a 2-week period.
- Completing three online surveys. The first survey will be upon entry to the study, the second survey will be emailed to you two weeks later and the third survey will be emailed to you at 6-months.
- Each survey will take 20 minutes to complete.
- The survey will include questions about you (age, gender, education), your diabetes, attitudes and knowledge about insulin, your understanding about diabetes and some questions about how diabetes makes you feel.
- You will also be asked to provide your name and email address. This is so we can link each of your surveys together and look at any changes in your responses over time. Any information you share with us will remain confidential.

After you have completed the first online survey on entry into the study, you will be allocated to one of two groups. You will receive a link to one of two web-based resources on insulin and type 2 diabetes. You have a 50% chance of being assigned to each group (like tossing a coin). You will have two weeks to explore the resource(s) allocated to you. We will send you an e-mail reminder during the two-week period to look at the resources. You will then be sent follow-up surveys at 2 weeks and 6 months.

Taking part in this study does not involve any change to your diabetes management or changes to the medications you take.

### Who is conducting this study?

Deakin University is conducting this study with funding from Sanofi-aventis Australia Pty Ltd (Sanofi). The study is coordinated by researchers (Principal Investigators) at The Australian Centre for Behavioural Research in Diabetes (ACBRD), a partnership for better health between Diabetes Victoria and Deakin University. The Principal Investigators take responsibility for the study. Participants will only be contacted by the research team including the principal investigators, the study project manager or research assistant.

### Are there any benefits for me personally?

People take part in studies like this for many reasons. For example:

- Taking part offers an opportunity to learn about and inform new diabetes research;
- Taking part offers an opportunity to think about your diabetes and reflect on your experiences;
- Taking part in research will help us to help other people with diabetes (either now or in the future).

In addition, participants who complete the study (i.e., access the web-based resource(s) and complete all three surveys) will be entered into a prize draw to win one of 20 \$100 department store gift cards that can be used at over 20 major retail stores in Australia.

### **Are there any risks to me?**

No, we do not believe that this study will cause you any harm or put you at risk of harm. **The study surveys include questions that may be sensitive or personal in nature (e.g. feelings about living with diabetes, income and employment status). However, we do not expect any question to cause you any distress.** If you should become upset during the survey, you may stop completing the questions at any time. We encourage you to contact the researchers to discuss this. The researchers will be understanding and supportive. You have the right to refuse to answer any question that makes you uncomfortable.

If, as a result of participation, you do become distressed, you may wish to seek further information and support from beyondblue: Beyondblue – National Information Line Ph: [REDACTED] or visit: <http://www.beyondblue.org.au/>

If you have any questions about your diabetes following the survey, we encourage you to contact your health professional or to call the National Diabetes Services Scheme Helpline: [REDACTED].

### **Can I withdraw at any time?**

Yes. **You are free to withdraw from this study at any time.** If you decide not to take part while completing an online survey, you can stop the survey and notify a member of the research team. Deciding not to take part (or to withdraw) will not affect your relationship with the ACBRD, Deakin University, Diabetes Victoria, or the study funder (Sanofi). If you withdraw from the study before, during, or immediately after you have completed the online surveys, we can remove any information you have shared from our analysis. However, once the study is closed your data will be de-identified and merged with other people's data. This means that you will not be able to withdraw the information you shared because we will not know which data are yours.

### **What will happen to my information?**

Any information you share with us will remain strictly confidential. The survey data will be stored in a database via the Deakin University secure network. Only the research team will have access to the password protected data. Once we have collected all of the data and are ready to analyse the results, the survey responses will be downloaded and de-identified. These files will not include any identifying information about you. Identifiable information (for example your email, name) will be stored in a password-encrypted excel spreadsheet. Any personal details you share about yourself (e.g. surname, contact details) for the purposes of enrolling you into the study will be destroyed (electronic files to be deleted) after you have completed the final survey. Safety follow-up interview data will be stored electronically (i.e. audio files). All data will be stored in a secure Deakin University computer file accessible only by the ACBRD research team. In accordance with government requirements, your data will be stored for at least fifteen (15) years following the publication of the results and then destroyed by erasing electronic files and shredding paper copies.

The overall results of the study may be published or presented in academic journals, at conferences, and in diabetes magazines and newsletters. Participants will be able to access any publications or reports resulting from the study on the ACBRD website ([www.acbrd.org.au](http://www.acbrd.org.au)). No-one will be able to identify you from any of the information we publish or present. The study funder may request access to the de-identified data. These data will not include any information that could be used to identify you. We will take great care to protect your identity. Your privacy is very important to us.

### Who is funding this project?

This project forms part of an Investigator Sponsored Study (SA-2017-11697) which is supported by Sanofi-aventis Australia Pty Ltd (Sanofi). Sanofi has no involvement in the study design, data analysis or interpretation and will not have any access to personally identifying information collected (e.g. contact details). De-identified study data may be shared with Sanofi, including survey results. Your personal and contact details will not be shared with Sanofi.

If you share with us (via the study surveys, e-mail or phone) any adverse events (safety issues) associated with therapeutic goods (e.g. medications) during your involvement with this study, we are required to report these to Sanofi. This could include any adverse events associated with the funder's products. Therefore, all the data that we collect from you will be screened for adverse events that may be associated with medications you take now or have taken in the past. In the event that you report an adverse event, we will contact you and ask a small number of additional questions (e.g. medication brand, dose, symptoms etc). If you decide not to answer the questions, this **will not affect your participation in the study**.

In addition, the researchers will notify the Deakin University Human Research Ethics Committee (DUHREC) of any adverse incidents, events, reactions that have a possible causal relationship with this research.

### Has this study been approved by an Ethics committee?

Yes. This study has been reviewed and approved by Deakin University's Human Research Ethics Committee (DUHREC), reference number 2020-073.

### Who can I contact about this study?

If you would like further information or have any questions about the study, please contact:

Dr Elizabeth Holmes-Truscott (e: [REDACTED] t: [REDACTED]),

Professor Jane Speight (e: [REDACTED] t: [REDACTED]), or

Dr Edith Holloway (e: [REDACTED] t: [REDACTED]), at the ACBRD.

To find out more about the work of the ABCRD, you may like to visit the website: [www.acbrd.org.au](http://www.acbrd.org.au).

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact:

The Human Research Ethics Office, Deakin University, 221 Burwood Highway, Burwood Victoria 3125, Telephone: [REDACTED], email: [REDACTED]. Please quote project number 2020-073.

<b>Consent Form</b>
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**Please tick the box at the bottom of the page to indicate your agreement with each statement.**

- I have read and I understand the Plain Language Statement.
- I freely agree to participate in this project according to the conditions in the Plain Language Statement.
- I have access to a copy of the Plain Language Statement and Consent form to print and keep.
- I understand and consent to completing three online surveys: at entry into the study, two-weeks and 6-months later. I will also be invited to explore web-based resources about type 2 diabetes and injecting insulin.
- I understand that if I report any adverse events (safety issues) associated with therapeutic goods (e.g. medications) I will be contacted and asked a small number of additional questions. If I decide not to answer the questions, this **will not affect my participation in the study.**
- I understand that the research team will not reveal my identity or personal details to anyone outside the research team, including where information is published or presented in any public form about this research study.
- I understand that the research team or the study funders may use the information I share in a closely related project, or an extension of the current research project, and that this information will be de-identified.

**I have read and understood the information above and agree to take part in this study.**

**I am ready to start completing the Attitudes Towards Insulin Study**

**Withdrawal Form**

*To be used for participants who wish to withdraw from the project*

**Date:** May 2020

**Full Project Title:** Development, Feasibility, and Efficacy of a Web-Based Intervention to Reduce Psychological Barriers to Insulin Therapy among Adults with Type 2 Diabetes (Stage 3: Full RCT)

**Reference Number:** 2020-073

**\*\*\*\*\*IMPORTANT\*\*\*\*\***

***Complete this form and return it to us only if you decide to WITHDRAW from the above-named study.***

I wish to withdraw from participating in the study entitled 'Development, Feasibility, and Efficacy of a Web-Based Intervention to Reduce Psychological Barriers to Insulin Therapy among Adults with Type 2 Diabetes (Stage 3: Full RCT)'. I do not want to take part in any additional study activities **and** I do not want the information I have already provided to be included in any analysis or study publications. I understand that withdrawing the information I have already provided will not be possible after completion of the second survey. I understand that withdrawing from the study will not adversely affect my relationship with any of the organisations conducting this study. I understand that withdrawing from the study will not affect the care or treatment I receive from any health professionals.

Participant's name (please print) .....

Participant's signature..... Date.....

Dr Elizabeth Holmes-Truscott

The Australian Centre of Behavioural Research in Diabetes

570 Elizabeth St, Melbourne, VIC 3000

T: [REDACTED]

E: [REDACTED]