




BMJ Open 'Is Insulin Right for Me?' Development of a theory-informed, web-based resource for reducing psychological barriers to insulin therapy in type 2 diabetes

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ABSTRACT

Objective To develop a theory and evidence-based web intervention to reduce psychological barriers towards insulin therapy among adults with non-insulin-treated type 2 diabetes (T2D).

Methods Salient psychological barriers towards insulin were identified from the literature and classified using the Theoretical Domains Framework (TDF). Relevant TDF domains were mapped to evidence-based behaviour change techniques (BCTs), which informed the content for each barrier. Acceptability was explored using cognitive debriefing interviews (n=6 adults with T2D).

Results 'Is Insulin Right for Me' addresses eight barriers, phrased as common questions: Does insulin mean my diabetes is more serious? Do insulin injections cause complications? Is it my fault I need to inject insulin? Will I gain weight? Will injecting hurt? What about hypos? Will injecting insulin be a burden? What will others think of me? BCTs, including persuasive communication and modelling/demonstration, were delivered using appropriate methods (eg, demonstration of the injection process). Participant suggestions for improvement included clear and direct messages, normalising insulin and avoiding confronting images.

Conclusions 'Is Insulin Right for Me' is the first theory and evidence-based, web intervention designed to reduce psychological barriers towards insulin therapy for adults with T2D. Evaluation is needed to determine its impact on negative appraisals and receptiveness towards insulin.

INTRODUCTION

Type 2 diabetes (T2D) is a progressive chronic health condition, characterised by insulin resistance and a decline in beta-cell function. Timely intensification of treatment is recommended to achieve and maintain optimal HbA1c (glycated haemoglobin; a measure of average blood glucose over 8–12 weeks).¹ For a person living with T2D, maintaining optimal HbA1c is imperative for preventing (and/or delaying) the onset of devastating macrovascular and microvascular

Strengths and limitations of this study

- A systematic, theory-based approach to develop a web-based intervention to reduce psychological barriers to insulin therapy among adults with type 2 diabetes.
- End-user feedback and expert input from a multi-disciplinary team to develop and refine the content.
- Relevance of the intervention may be limited due to the exclusion of published studies conducted in non-Western countries that focused on culturally specific barriers.
- We relied on existing published literature to identify salient psychological barriers, however, other unique barriers to, and enablers of insulin initiation exist (eg, factors associated with clinical care).

complications,² which are associated with a significant decline in quality of life and mental health outcomes.³

Insulin therapy is the most effective treatment to maintain optimal blood glucose levels⁴ and early consideration of insulin initiation is recommended by T2D clinical management guidelines.⁵ Notwithstanding, among adults with T2D, insulin is typically delayed beyond clinical need.⁶ Several important factors contribute to this delay, including clinical inertia among health professionals⁷ and a preference to avoid insulin among people with T2D. Furthermore, up to one-quarter of people with T2D for whom insulin is clinically indicated report being unwilling to commence insulin.⁸ Psychological insulin resistance (PIR) refers to the reluctance to commence, use as recommended or intensify insulin therapy.⁹ It is based on a person's negative attitudes or beliefs about insulin therapy, such as the necessity for insulin, its side effects, its physical and social impact and

what insulin symbolises about their health and identity.⁹ These negative attitudes are significantly associated with low intention to initiate, and actual uptake of, insulin treatment.^{8 10 11}

Despite a wealth of empirical studies highlighting salient factors that underlie PIR, including feelings of failure and diabetes progression, fear of injecting and misconceptions about insulin,¹² little is known about effective strategies that can overcome these attitudes and beliefs. Cross-sectional studies show that healthcare professionals (HCPs) who address injection concerns by showing and/or demonstrating the injection process, explain the benefits of insulin, and adopt a collaborative, communication style are perceived by participants as helpful for overcoming PIR.^{13–15} However, it remains unclear whether these strategies effectively target the underlying determinants of behaviour (ie, attitude/belief), nor have they been rigorously evaluated to determine their effect on negative insulin appraisals. Furthermore, these ‘helpful’ strategies are reported retrospectively by participants.^{13–15}

To improve the uptake of insulin therapy, interventions at multiple levels are required. In addition to reducing HCPs clinical inertia and systemic barriers,¹⁶ there is also a need for person-centred interventions available outside of the clinical setting that directly target the beliefs and attitudes people with T2D may have about insulin therapy. Given the sheer number of people living with T2D and reporting concerns about insulin globally,¹⁷ effective strategies to overcome PIR that are scalable are needed. Online interventions provide the ideal platform for wide reach, with minimal burden on limited healthcare resources. Web-based interventions enable the cost-effective administration of highly accessible specialist behaviour change programmes that can use content tailored to user characteristics, including interactive exercises (with immediate feedback), animations and audio/video resources. Online self-management interventions for

T2D with clear theoretical groundings and behaviour change techniques show favourable impact on health behaviours and health-related outcomes.¹⁸

Therefore, we aimed to develop an evidence-based, theoretically grounded web-based intervention targeting salient barriers to insulin therapy for adults with non-insulin-treated T2D. We also aimed to improve the acceptability and relevance of the resource through the engagement of adults with T2D in its development and refinement.

METHODS

Development of the ‘Is Insulin Right For Me’ web-based resource

We followed a systematic development process guided by the UK Medical Research Council (MRC) framework.¹⁹ We describe the *intervention development* stage of the MRC framework (identifying the evidence base and developing a theoretical understanding of the underlying processes of change) drawing on detailed reporting guidance (figure 1).^{20 21} Concepts of a participatory design approach²² were incorporated, by exploring user acceptability (eg, relevance, ease of use) and refining the content in line with the needs and preferences of adults with T2D.

The intervention development process described here was carried out prior to a feasibility trial, details of which are available on the trial registry website (ACTRN12619001382167).

Patient and public involvement

The public (end-users) were involved in the refinement of the web-based resource content. Patients and/or public were not involved in the development of the study design, conduct or dissemination of the study findings.

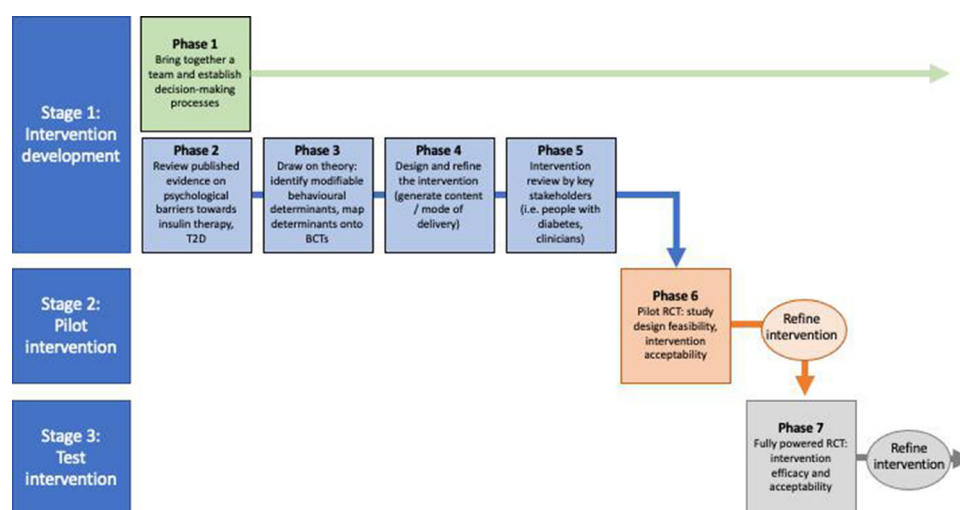


Figure 1 Intervention development framework.*Informed by: MRC Framework (Craig *et al.*¹⁹ 2008); Guidance for reporting intervention development studies (guided) (Duncan E *et al.*²⁰ 2020, O’Cathain A *et al.*²¹ 2019). BCTs: Behaviour Change Techniques; MRC, Medical Research Council; RCT: Randomised Controlled Trial; T2D: Type 2 Diabetes.

Step 1: understanding the target behaviour(s)

The initial step in the MRC framework is the identification of relevant, existing evidence.¹⁹ An electronic database search of the literature reporting on negative beliefs and attitudes that contribute to PIR was conducted using PubMed, Embase, Web of Science, PsycINFO and Google Scholar. Searches were performed in March 2019. Databases were searched using a combination of Medical Subject Headings and keywords relating to 'type 2 diabetes', 'insulin therapy', 'psychological insulin resistance', 'beliefs', 'attitudes' and 'barriers'. Boolean operators ('AND' and 'OR'), proximity operators ('ADJ' and 'N') and truncation were incorporated into the search strategy as required to cater for the different use of terms. Quantitative and qualitative empirical studies reporting on adults aged ≥ 18 years with T2D (both non-insulin and insulin treated) were included in the search. Quantitative studies were required to report on the proportion of participants who endorsed the psychological barrier. Only peer-reviewed articles in English were included with no restrictions on the year of publication.

References identified in the search were imported into EndNote V.X9.²³ Following the removal of duplicates, studies were then assessed by the first author (EEH) for relevance by screening abstracts and full-text articles. A second author confirmed study relevance and suitability for inclusion (JS). The first author (EEH) extracted data from each of the included studies using a template discussed and agreed on with a second author (JS; online supplemental file 1).

Step 2: select target behaviour(s)

In order to determine which of those factors identified in stage 1 were most salient for adults with T2D, two authors (JS and EEH) discussed the evidence pertaining to each, including: the proportion (upper and lower range of crude percentages) of participants who endorsed each psychological barrier; if the proportion of participants endorsing the barrier differed significantly between those willing versus those unwilling to initiate insulin; the extent to which the barrier is modifiable (and within the scope of this intervention); and the extent to which barriers could be collapsed into themes. These psychological barriers were then discussed with coauthors (TS and EH-T) until consensus was reached. All authors reached agreement on the barriers selected for inclusion in the resource.

Step 3: identify modifiable behavioural determinants using theory

In step 3 we identified the underlying determinants of each salient psychological barrier. A review of behaviour change theories and theoretical frameworks was carried out. Many determinants mapped on to the 14 domains in the Theoretical Domains Framework (TDF),²⁴ hence this framework was selected. The TDF is comprised of 14 theoretical domains which summarise the theoretical constructs from 33 theories of behaviour change.²⁴ The 14 domains provide a framework for a more

comprehensive behavioural diagnosis, to identify the drivers of behaviours, and to guide the subsequent identification of suitable intervention functions that can be used to promote change in these behaviours. The TDF has been validated for use as a method of theoretically assessing health behaviours to inform intervention development.²⁴ Two authors (EEH and JS) initially applied the TDF and identified the relevant domains to characterise determinants of each psychological barrier. A consensus exercise was then undertaken. Four external senior research academics, with experience in behaviour change, independently reported their agreement with the coding. Where the rater disagreed with the TDF domain, they were asked to provide a reason for their decision. Raters were also asked if they considered any other TDF domains were relevant to the barriers. Discrepancies were discussed among the group until consensus was reached.

Step 4: identify content and implementation options

Determinants were mapped onto behaviour change techniques (BCTs) to overcome the modifiable barriers. BCTs are the smallest components of behaviour change interventions that on their own have the potential to change behaviour. BCTs selected to be used in the intervention were identified from an extensive taxonomy of 93 consensually agreed, distinct BCTs.²⁵ In addition to the taxonomy, we also reviewed BCTs which have demonstrated effectiveness in trials of implementation interventions for diabetes care.^{18 26} We also reviewed strategies used by HCPs to address PIR in published studies. The use of APEASE (Affordability, Practicality, Effectiveness, Acceptability, Side effects, Equity)²⁷ provided evaluative criteria and guided the final selection of BCTs (online supplemental file 2).

Step 5: generating content and mode of delivery

The website structure and key messaging responded to the identified salient psychological barriers (step 2) and was informed by the relevant BCTs (step 4). We identified key aims for each intervention and discussed appropriate methods of application (eg, text, quizzes, videos).^{18 28} For example, quotes and audio case studies from people with diabetes were used to normalise beliefs and attitudes; improving expectations about future insulin use, as well as modelling behaviours and improving self-efficacy through observational learning. The key messaging for the intervention components drew on self-determination theory (SDT).²⁹ SDT emphasises personal autonomy and self-direction to satisfy needs and enhance effective behavioural change. It has demonstrated relevance to the diabetes context, particularly for self-management programmes designed to support people living with T2D.^{30 31}

The intervention content was also informed by the authors' extensive research in the area of attitudes to insulin therapy and insulin uptake.^{8 11 16 32} We took an iterative approach to generating content, involving weekly or biweekly discussions between members of the research

team (EEH, JS, TS and EH-T). An experienced multi-disciplinary team as well as peer reviewers (endocrinologist, general practitioner, credentialed diabetes educator, psychologist) provided clinical input on the resource. Peer reviewers were invited for their expertise; to ensure the content accuracy and consistency with Australian medical guidelines and standards; as well as their experience working with people with T2D. Finally, the content was reviewed for clinical accuracy by credentialed diabetes educator and was proofed by a professional editor, prior to being published on the website.

Consumer feedback on the web-based resource

Study design

This was a qualitative study involving individual face-to-face semi-structured cognitive debriefing interviews.

Participants

Australian adults (aged 18–75 years) with a self-reported diagnosis of T2D were eligible to take part. Participants already using insulin therapy were eligible to participate as it is expected that this group would offer important insights into the needs of people with T2D at the time of insulin initiation. Participants were required to attend a face-to-face interview in Melbourne, read and write in English and provide written informed consent.

We aimed to recruit between 5 and 10 adults with T2D, deemed sufficient to inform initial iterations to the web-based resource,³³ including a balanced split by gender (women, men), age (≤ 60 , >60) and diabetes treatment (non-insulin-treated, insulin-treated). Participants were recruited using convenience sampling through websites, e-newsletters/blogs and social media (Twitter, Facebook) via the researchers' affiliated professional accounts (eg, Deakin University, Australian Centre for Behavioural Research in Diabetes) and invited to contact the research team (via email or telephone).

Procedure

On contact, potential participants were asked to provide their first name, preferred method of contact and respond to eligibility screening and purposive sampling questions. Those eligible received a copy of the plain language statement (PLS) and consent form via email and were asked to read the PLS and confirm whether they wish to proceed, at which time the interview was scheduled with consenting participants. Participants returned their signed consent form via email or handed it to the researcher prior to participation.

Cognitive debriefing interviews were conducted by the study project manager (EEH). Two authors (EH-T and JS) each observed one interview. The interviews lasted approximately 60 min and were conducted at two locations in Melbourne, Victoria. With participants written consent, interviews were audio recorded. At the completion of the interview participants were asked to complete a one-page demographics form (including age, gender, country of birth, highest level of education, employment

status, year of diabetes diagnosis and primary diabetes treatment).

Participants who completed the study were provided with a \$A20 e-Gift department store voucher as a token of appreciation.

Interview schedule

Participants were asked to provide feedback on three of the eight resource topics (online supplemental file 2), selected at random. The content was presented (via PowerPoint slides), in a format simulating web-based delivery, which the participant could scroll through at their own pace. Participants were encouraged to 'think aloud', verbalising their thoughts as they read through content with occasional probing by the interviewer for clarification. Participants were also asked to provide feedback on the relevance, comprehension and acceptability of the resource of the content, images, quotes and quizzes.

Qualitative analysis

Interview recordings were reviewed by the study team and areas for resource content and design development/refinement were identified. Thematic analysis was used to identify patterns or themes in the text (codes) across the interviews and themes were defined/named. Feedback was reviewed and discussed by the research team (EEH, JS, TS and EH-T). All feedback was incorporated in the web-based resource unless it was determined by the web developer not to be feasible.

RESULTS

Intervention development

Stage 1: understanding the target behaviour(s)

Fourteen empirical studies reporting on attitudes and beliefs contributing to PIR were identified from the literature search (n=6 cross-sectional, n=5 qualitative studies and n=3 randomised controlled trials (RCTs)). The search highlighted 12 salient psychological barriers among non-insulin-treated and insulin-treated adults with T2D (online supplemental file 1).

Stage 2: selection of target behaviours

From the 12 barriers identified in our literature search, we selected eight psychological barriers to address in the 'Is insulin right for me' web-based resource (table 1).

'Taking insulin makes me more dependent on my doctor' was omitted, as this barrier was reported only in studies using the Insulin Treatment Appraisal Scale and not spontaneously raised in qualitative research. Furthermore, studies (online supplemental file 1) found no significant differences between the proportion of participants who endorsed this barrier among those willing compared with those unwilling to initiate insulin. Where the intervention function for barriers was considered to be analogous to one another, and the key content overlapping, these were collapsed into an overarching theme.

Table 1 Rationale for retaining barriers identified from literature review in the web-based resource (step 2)

Barrier	Range	Sig difference between groups*	Retained (yes/no)
1. Diabetes has become worse	21%–85%	Yes (n=2/3)	Yes
2. Personal failure	9%–73%	Yes (n=3/3)	Yes
3. Fear/anxiety of injecting	8%–67%	Yes (n=3/3)	Yes
4. Self-efficacy/capability†	22%–61%	Yes (n=2/3)	Yes†
5. Lifestyle changes/flexibility/loss of control†	8%–82%	Yes (n=2/2)	Yes†
6. Side effects: hypoglycaemia	38%–76%	No	Yes
7. Side effects: weight gain	15%–53%	No	Yes
8. Causes complications	7%–46%	Yes (n=1/2)	Yes
9. Embarrassment of injecting in public‡	16%–58%	No	Yes‡
10. Perceived as sicker‡	34%–55%	No	Yes‡
11. Treated differently‡	50%–76%	No	Yes‡
12. Dependent on general practitioner	39%–55%	No	No

Range, minimum and maximum proportion of participants who endorsed barrier reported in published studies (online supplemental file 1).

*Sig difference between groups=participants unwilling to initiate insulin were significantly more likely to endorse barrier compared with those who were willing ($p<0.05$); n=number of studies who reported group differences.

†Collapsed into single theme: insulin therapy will add to the burden of managing my diabetes.

‡Collapsed into single theme: how will others perceive me (social influences).

Three barriers (embarrassment of injecting insulin, others will see me as sicker, family and friends treating me differently) were collapsed into the theme ‘what will others think of me’. Two barriers (low self-efficacy and lifestyle changes) were also collapsed into one theme ‘will injecting insulin be a burden’.

Step 3: identify modifiable behavioural determinants using theory

The TDF analysis identified eight domains (knowledge; skills; social role and identity; beliefs about capabilities; beliefs about consequences; environmental context and resources; social influences; emotion) as determinants of behaviour (table 2). The eight barriers most frequently mapped to the following TDF domains: emotion—fear of the injection process, side effects and complications; beliefs about capabilities—beliefs around personal failure and low self-efficacy with regards to the injection process; and beliefs about consequences—associated with the side effects and complications of insulin therapy.

Step 4: identifying content and implementation options

The final selection of BCTs and mode of delivery is summarised in online supplemental file 2. This process was informed by the TDF and empirical evidence about the effectiveness of BCTs. Consideration was also given to what mechanisms of change would be relevant for this population, likely to be feasible, and appropriate for web-based delivery (APEASE²⁷ criteria).

Step 5: generating content and mode of delivery

The eight barriers targeted in the ‘Is insulin right for me’ resource are phrased as common questions, for example, ‘Does insulin mean my diabetes is more serious?’. Before accessing the intervention content, users preview a key summary statement which directly responds to the

question and provides a succinct overview. Each of the eight ‘active interventions’ are presented on a separate web page. Informed by the BCTs, the format varies for each barrier including text, quizzes, imagery, video demonstration, case studies (with audio recordings) and personal quotes from people with T2D (online supplemental file 2). For example, for the barrier ‘Does Insulin mean my diabetes is more serious’, we aimed to challenge beliefs using a quiz to highlight that insulin may be recommended at any stage; provide information and present arguments in favour of the target behaviour (persuasive communication), and present text in an autonomy-supportive style in line with SDT.²⁹ We aimed to provide a brief and concise ‘active intervention’ for each barrier (200–500 words; 5-min read) to facilitate user engagement.

The resource also includes information about the benefits of insulin therapy: (1) that it lowers blood glucose levels; (2) can lower your risk of long-term health complications; (3) can make you feel better; and (4) can make managing your diabetes more flexible. Links to other resources about T2D and insulin available from the National Diabetes Services Scheme, and study information are also available through the resource. The web-based resource was developed over 8 months (March to October 2019).

Participant acceptability and feedback

Demographic characteristics

We conducted six cognitive debriefing interviews with adults with T2D (between July and August 2019). Three participants were women, three were born in Australia and three had a higher university degree. The mean age at T2D diagnosis was 42.7 years (SD=11.04) and 67%

Table 2 Identifying modifiable determinants (attitudes, beliefs) of behaviour (insulin initiation) using theory and mapping these to BCTs

Using theoretical framework(s), which barriers and enablers need to be addressed? (step 2)	Within which theoretical domains of the TDF do the barriers and operate? (step 3)	Intervention components (BCTs) identified from the literature to overcome the modifiable barriers (step 4)
Insulin therapy means my diabetes has become much worse; diabetes has progressed; my diabetes is at an end stage	Beliefs about consequences Emotion	Persuasive communication; challenge beliefs; information about the relationship between the behaviour and its possible or likely consequences
Insulin therapy represents personal failure as a result of inadequate self-management; injecting insulin is punishment	Beliefs about capabilities Emotion	Increasing self-confidence/self-efficacy in diabetes self-care efforts; persuasion; forming/shaping beliefs and knowledge about diabetes and insulin; information provision (normative information— how common IT is in the population)/comparison
Fear/anxiety of injecting insulin with a needle and/or fear of the pain	Emotion Beliefs about capabilities	Information provision; manage expectations/feelings; coping skills; modelling/demonstration; forming/shaping beliefs; social processes of encouragement/support; use of imagery
Fear of hypoglycaemia (hypos) associated with insulin therapy	Emotion Beliefs about consequences	Information provision; persuasive communication; salience of consequences/side effects
Insulin therapy causes weight gain	Emotion Beliefs about consequences	Information provision; persuasive communication; anticipated regret; decision-making— highlight pros vs cons of IT (eg, possible weight gain vs benefits of IT), salience of consequences/side effects; motivational interviewing; cognitive restructuring
Insulin therapy causes diabetes-related complications	Knowledge Emotion	Information provision (shaping beliefs/knowledge); information about health behaviour and outcome; persuasive communication
Insulin will add to the burden of managing diabetes; inconvenient; makes life less flexible	Environmental context and resources Beliefs about capabilities Knowledge	Information provision; persuasive communication; planning; goal setting; pros vs cons
How will others perceive me? (eg, other people see me as a sicker, others may treat me differently, stigma/embarrassment of injecting in public)	Social influences Social role and identity Emotion	Modelling/demonstration of behaviour by others; social processes of encouragement, and support; restructuring the social environment; comparison of behaviour; information provision, persuasive communication, information about others' approval, social support, identification of self as role model.

BCTs, behaviour change techniques; IT, Insulin therapy; TDF, Theoretical Domains Framework.

(n=4) were not currently managing their diabetes with insulin injections.

Participant feedback

The main themes identified from the participant interviews are summarised in [table 3](#). Overall, the resource was reported to be engaging and useful. Suggestions for improvement included clear and direct messages, particularly with regards to 'Will injecting insulin be a burden?'. Participants felt that the intervention content minimised

the effort, particularly the mental load, associated with insulin therapy. For the barrier 'Does insulin mean my diabetes is more serious?' participants thought it was important to state that 'your body changes and insulin therapy is just another change to taking care of your diabetes'. It was suggested for the barrier 'Is it my fault?' to normalise insulin therapy and highlight how common it is for adults with T2D to inject insulin. With regard to the barrier 'What will others think?', participants were less

Table 3 Improvements to the web-based resource suggested by participants (cognitive debriefing interviews; n=6)

Theme	Example quote	Example of refinement to the resource
Neutral imagery	'Don't use images of people injecting insulin early on in the resource—people with T2D may have a fear of injecting and this could be quite confronting—don't use images with face. Cartoons of people injecting may work better'	Images are of cartoons and close up images of a person injecting insulin (no faces)
Will injecting insulin be a burden? Avoid minimising effort in injecting insulin	'Don't want to be told "you can do it". Its condescending and doesn't answer my question. Explain the effort involved...of course it is going to take effort...be upfront'	Key messaging was revised in line with participant feedback, for example, 'You may feel like injecting insulin is another thing to add to your 'to do' list—but this can make it easier to live your life as you want'
Is it my fault I need to inject insulin? Normalise insulin therapy	'Include simple percentages of how many people use insulin'	Inclusion of percentage of Australian's who will need insulin injections: 'To stay healthy 1 out of every 2 Australians with T2D will need insulin injections within 10 years...'
Does insulin mean my diabetes is more serious? Insulin therapy is just another change to your medication	'Emphasise insulin is right for you at this "stage"—you haven't been given the wrong information before by your health professionals previously, it's just that your condition has changed'	Key messaging was revised in line with participant feedback, for example, 'So, if your health professional recommends insulin to you, it's because insulin injections are the best treatment option for you right now, to help you to stay healthy'
What will others think of me? What will others think is about others in society and not family	'If I'm on insulin I wouldn't care what family (grandchildren) think of me but I would care more about what other adults think of me'	Strategies of talking to family members about starting insulin were removed and updated with managing feelings about injecting in public
What will others think of me? Include case studies that are relatable	'Remove or delete case study about (...) as this is an extreme case and will not resonate with many people. Consider using a more general case study'	Case study about person experiencing difficulties with her family accepting insulin (culture) was revised with a general example of 'friends' treating you differently
Will injecting insulin be a burden? Acknowledge practical issues (will injecting be a burden)	'Content should address real-life practical issues and concerns about the impact of insulin injections on life, for example, travelling with insulin'	Content was revised to focus on the practical issues associated with injecting insulin and the importance of planning, for example, 'You can inject anywhere. You can take insulin with you wherever you go (even on planes). As long as you're comfortable, there's no need to find a special room or private place to inject insulin'

T2D, type 2 diabetes.

concerned about family and friends and more so about society (workplaces, public places) and how others would react. Further feedback was to ensure case studies and imagery were relevant and relatable, and that imagery/demonstrations of insulin injection would minimise feelings of fear and anxiety (eg, use of cartoons).

Where feasible, and consistent with the underlying theory and evidence-based approach used for development, the content was revised to reflect participant feedback (table 3). For example, the insulin injection imagery and video content was not included on any study advertisements or the home page, and where this was included, no faces were shown. We revised the 'What will others think?' barrier according to participant feedback. Tips for talking to family and friends about insulin therapy (restructuring the social environment) were removed

and replaced with case studies of how people with T2D had responded to concerns about other people's reactions to injecting.

DISCUSSION

This study describes the development of 'Is Insulin Right for Me', a self-directed, web-based resource to address eight salient psychological barriers, and improve receptiveness, to insulin therapy among adults with T2D. To our knowledge, it is the first intervention designed specifically to address PIR, and developed systematically based on evidence, theory and user preferences.

Each of the eight 'active interventions' (corresponding with eight identified barriers) uses evidence-based and practical strategies to deliver the BCTs, such as

modelling/demonstration, persuasive communication and information provision. The relevant BCTs we selected have been reported elsewhere,^{13 15 34 35} that is, that HCPs who engage in the identified behaviours are perceived by people with T2D as more helpful, are associated with greater acceptance of insulin and more successful initiation and persistence. Modelling and demonstration of the injection process has been highlighted as particularly important for reducing PIR¹³ and is consistent with common clinical recommendations.³⁶

This study has several strengths. To our knowledge this is the first study to use a systematic, theory-based approach in the development of a behaviour change intervention to reduce psychological barriers to insulin therapy among individuals with T2D. The behavioural approach to intervention design (using the TDF) allowed for informed decision-making about which active ingredients to include in the intervention. It is anticipated that this approach will increase the potential intervention efficacy for reducing PIR, provide evidence for the effectiveness of the relevant BCTs included in this resource, as well as replication of the intervention components in other settings. A further strength was the formative and iterative approach taken to develop and refine the resource content, which accords with MRC guidance on complex behaviour change interventions.¹⁹ End-user feedback allowed refinements to be made to content, images and website layout from an early stage of the development process. We also gathered expert input from a multidisciplinary team to develop and refine the content, including review of the clinical content by diabetes health professionals to ensure accuracy and relevance for the target population.

The current study is not without limitations. Some published studies, conducted in non-Western countries, were not included in our review as findings were culturally specific and not applicable to the general Australian population. Therefore, the extent to which this resource is generalisable and culturally relevant to non-Western countries, or unsampled culturally and linguistically diverse communities within western countries, may be limited. However, this systematic, theory-driven and evidence-based development process will have relevance for researchers and practitioners internationally, especially considering the current paucity of evidence-based interventions to address PIR.

The barriers identified and targeted by this intervention are not exhaustive. We relied on existing published literature (which is largely cross-sectional), and, included only psychological barriers raised by people with T2D. Other unique barriers to insulin initiation exist, such as factors associated with health systems and clinical care (eg, clinical inertia, level of support from HCPs, access, cost).³⁷ Facilitators of insulin initiation, such as the perceived benefits, were not targeted explicitly within our intervention using evidence-based BCTs. Overall, research is broadly lacking into personal attitudes and beliefs that enhance insulin initiation. Further studies could explore

and evaluate enablers of insulin initiation and receptiveness and develop strategies to enhance these in the target population. Furthermore, a small convenience sample provided feedback on the resource. Evaluation of the acceptability and relevance of intervention content and mode of delivery among diverse and representative samples is needed with further feedback already sought from a larger sample in our pilot study and a full RCT.

Overcoming barriers to insulin initiation and improving timely uptake has important implications for the health outcomes of people with T2D. Importantly, barriers to treatment initiation and intensification are multifaceted. This resource has considerable potential to play an important role in shaping the beliefs and attitudes of people with T2D towards insulin therapy, that is supplementary to clinical care, and with minimal burden on HCPs' time and clinical consultations. Future studies could investigate the short-term and sustained impact on receptiveness to further intensification of insulin and medication-taking behaviours.

Our literature review highlights that BCTs, such as modelling and demonstration, may already be used in clinical settings, without much awareness of the underlying theory to explain how these strategies are associated with behaviour change. This study provides a framework from which HCPs can identify evidence-based strategies and theory-informed techniques to respond to psychological barriers to insulin therapy, which may optimise their implementation in routine care.

We have conducted a pilot RCT to assess the acceptability and feasibility of the intervention (Holmes-Truscott *et al*, in preparation), and plan to proceed with a fully-powered RCT to test the effect on attitudes and willingness to initiate insulin. If found to be effective, we anticipate the self-directed and web-based mode of delivery to be a low-cost approach, that has the potential for considerable scale-up and reach. National and/or state-based Australian diabetes organisations may host the web-based resource and offer free access online to all Australians. Future research could seek to evaluate real world, implementation outcomes to improve sustainable adoption and investigate, using a clinical-based trial, the impact of the intervention on actual insulin uptake (and consequently on HbA1c) among adults with T2D for whom treatment intensification is clinically indicated.

CONCLUSIONS

We report on the systematic development of a novel web-based resource, 'Is Insulin Right for Me', designed to reduce psychological barriers to insulin therapy and increase receptiveness among adults with non-insulin-treated T2D. It is the first such intervention to be informed by theory and evidence-based BCTs, as well as user preferences, and has considerable potential to reach the large population of adults with T2D who may benefit from timely insulin initiation.

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