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PSYCHOSOCIAL ASPECTS (S JASER, SECTION EDITOR)

Assessing Psychological Insulin Resistance in Type 2 Diabetes: a Critical Comparison of Measures

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Abstract
Purpose of Review This study aims to examine the operationalisation of 'psychological insulin resistance' (PIR) among people with type 2 diabetes and to identify and critique relevant measures.
Recent Findings PIR has been operationalised as (1) the assessment of attitudes or beliefs about insulin therapy and (2) hypothetical or actual resistance, or unwillingness, to use to insulin. Five validated PIR questionnaires were identified. None was fully comprehensive of all aspects of PIR, and the rigour and reporting of questionnaire development and psychometric validation varied considerably between measures.
Summary Assessment of PIR should focus on the identification of negative and positive attitudes towards insulin use. Actual or hypothetical insulin refusal may be better conceptualised as a potential consequence of PIR, as its assessment overlooks the attitudes that may prevent insulin use. This paper provides guidance on the selection of questionnaires for clinical or research purpose and the development of new, or improvement of existing, questionnaires.

Keywords Type 2 diabetes · Insulin therapy · Psychological insulin resistance · Treatment intensification · Questionnaire · Measurement

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Introduction

International guidelines emphasise the early consideration and initiation of insulin therapy among people with type 2 diabetes (T2D) for whom target glycaemic outcomes are not achieved with maximum oral hypoglycaemic agents and/or non-insulin injectables [1, 2]. However, research suggests that both initiation and intensification of insulin are commonly delayed beyond clinical need [3•, 4, 5, 6•, 7–10]. Causes of delay are multi-faceted, including, for example, healthcare systemic barriers [11, 12] and clinical inertia among healthcare professionals (HCPs) (i.e. delaying recommendation/prescription beyond clinical need) [3•, 13]. Delay may also be due to the person with T2D experiencing a phenomenon known as 'psychological insulin resistance' (PIR). Systematic reviews of PIR have synthesised relevant qualitative and quantitative literature over the past two decades, providing an overview of commonly reported barriers to insulin use among people with T2D and known correlates and determinants of PIR [14, 15, 16••, 17]. PIR has been operationalised in various ways, and several tools developed to measure PIR, but no comprehensive review of measurement has been conducted to date. Therefore, we aim to clarify the operationalisation of PIR and to identify and evaluate measures of PIR, in terms of questionnaire design, conceptual focus and psychometric properties, as well as provide recommendations for future research.

Operationalising Psychological Insulin Resistance

In the context of T2D, PIR is commonly defined as a reluctance to use insulin therapy due to negative attitudes (i.e. concerns or fears) about the therapy [14, 15, 18]. PIR has been operationalised in terms resistance to using insulin therapy (1) and attitudes towards insulin therapy (2). The implications of this are discussed in the subsequent sections. In contrast to the vast literature exploring PIR, it has been suggested that 'receptiveness' to insulin therapy is a common experience and that the phenomenon of PIR may have been overstated [19]. This poses the question of whether receptiveness to insulin is best conceptualised as acceptance of insulin use, the absence of negative attitudes and/or the presence of positive attitudes towards insulin therapy. These issues are discussed further below.

PIR research has most commonly focused on adults with non-insulin-treated T2D with reference to insulin uptake. However, PIR is not limited to this treatment group and may have explanatory value in relation to ongoing use and resistance to further treatment intensification. For example, among those with insulin-treated T2D, psychological barriers to insulin use have been cited as reasons for self-reported insulin omission [20–22] and qualitative research has highlighted negative attitudes towards insulin intensification [19, 23•] and self-titration [24••]. In this review, the measurement of PIR is considered across all stages of treatment progression.

Resistance to Insulin Therapy

The limited data available suggest that 20–43% of people with T2D for whom insulin is recommended refuse it, depending on the support received, the study setting (i.e. clinical trial, real-world cohort study) and population [25–27]. Studies investigating insulin refusal typically do so using a proxy measure, i.e. the proportion of people who report being hypothetically (un)willing to initiate insulin, generally assessed using a single-item measure [28–37]. For example, 'If your doctor recommended that you start insulin, how willing would you be to take it?' [30]. Rates of hypothetical 'unwillingness' vary considerably across samples, for example, an international study reported 6% of participants in Spain were 'not at all' willing to initiate insulin compared to 37% in Italy [30]. For those already using insulin, similar single items have been used to measure willingness to "titrate insulin treatment, if advised" [36] or administer additional injections per day [38].

Utility of a Single-Item Measure

Within a clinical context, a single-item measure may be a practical, quick and easy screening tool to identify people with T2D who face barriers to insulin initiation and may need additional support to promote timely treatment intensification. Indeed, a recent prospective study has demonstrated the predictive validity of this single item in terms of actual insulin uptake: adults with T2D requiring treatment intensification who were hypothetically 'very willing' to commence insulin at baseline were six times more likely to be using insulin at follow-up compared to those who were 'not at all' [39••]. However, single items have clear psychometric limitations: there is typically no information on their origin or development history, internal consistency reliability cannot be computed for a single item, they are more vulnerable to random measurement errors and there is greater scope than with multi-item measures for ambiguity of interpretation of the meaning of the item.

Furthermore, a single item focused on 'willingness' provides no insight into the reasoning behind any resistance and, therefore, no direction for intervention. For clinical and research purposes, identifying and addressing barriers may be equally as important among those who report being willing to use insulin therapy as for those reporting unwillingness. Indeed, receptiveness may be a consequence of several factors (e.g. influence of family and friends [40••], the clinician/patient relationship and decision-making dynamic [41]) and does not necessarily equate to the absence of concerns about insulin, which may impact on treatment transition. Recent research suggests that the 'necessity-concerns framework' may have value in explaining acceptance of insulin therapy [40••]. In this framework, people with T2D can concurrently hold both negative and positive attitudes towards insulin, and the decision to use insulin therapy is a negotiation between these attitudes. A focus on resistance or receptiveness alone is not, in itself, a clinically useful operationalisation of PIR. To understand the individual's reasoning, attitudes to insulin therapy must be investigated.

Attitudes to Insulin Therapy

Qualitative research [15–17] has identified numerous psychological barriers to insulin therapy among adults with T2D, including, for example, injection-related anxieties, low self-efficacy, concerns about side-effects (i.e. hypoglycaemia, weight gain), inaccurate health beliefs (e.g. insulin being a cause of long-term diabetes-complications), concern about financial burden of treatment, doubts about the effectiveness or necessity of insulin, concern over apparent diabetes progression and feelings of personal failure, concerns about the impact of treatment on social relationships and freedom and flexibility and perceived diabetes stigma. Studies have also identified more general barriers related to religious and cultural norms and values. For example, a distrust of Western medicine [42, 43], a strong sense of fatalism or stronger reliance on

faith than medicine [27, 44] and influence of community and family values in decision-making [45].

Over the past decade, there has been a considerable research focus on developing quantitative measures of these attitudes. Three measures of PIR were published in 2007: the 14-item 'Barriers to Insulin Treatment' (BIT) [46], the 20-item 'Insulin Treatment Appraisal Scale' (ITAS) [47] and the 14-item 'Study the Hurdles of Insulin Prescription' (SHIP) [38]. The ITAS, BIT and SHIP were designed for Western populations, and aspects of PIR assessed may lack cross-cultural relevance. For this reason, the 13-item 'Chinese Attitudes to Starting Insulin Questionnaire' (Ch-ASIQ) [48] and the 18-item 'Korean Psychological Insulin Resistance scale' (K-PIR) [49] were developed with the aim of producing measures of PIR both culturally and linguistically appropriate to those populations. The development and validation of the K-PIR was published in Korean only, and therefore, a full critical review of this questionnaire is not provided here [49]. Finally, the 22-item 'Beliefs about Insulin Scale' (BIS) was published most recently [50••]. Table 1 summarises the development history and psychometrics properties of the five PIR questionnaires published in English-language journals (i.e. BIT, ITAS, SHIP, Ch-ASIQ, BIS), as well as the questionnaire characteristics, e.g. length, subscales, scoring, language availability and subsequent uptake.

In addition, several studies have employed study-specific items or scales to measure attitudes to insulin therapy (e.g. [26•, 29, 30, 34, 63]). These are typically unvalidated with little description of item wording, development process or psychometric properties and are therefore excluded from this review. Finally, a number of other questionnaires are relevant to PIR but either focus too specifically on a single aspect, or domain of, PIR (e.g. fear of self-injecting [64], concerns about hypoglycaemia [24••]), or assess satisfaction with insulin without identifying factors influencing satisfaction (e.g. [65]). These measures are not discussed further.

Conceptual Focus and Content Validity

The process undertaken to develop PIR questionnaires varies considerably (see Table 1). As reported, the development of the ITAS and BIT was informed by literature review and clinical experience. The iterative development and refinement of the SHIP involved a three-phase process including qualitative research with the target groups, subsequent cognitive debriefing of items and a review by an HCP expert panel. In contrast to other measures, the development of the BIS was theoretically driven and the item pool was developed and reviewed by experts to reflect the adopted cognitive-behavioural theoretical framework [50••].

Appendix 1 illustrates the specific aspects of PIR measured by each questionnaire and the conceptual overlap between questionnaires. The themes and sub-themes used to group questionnaire items is based upon the current authors' subjective interpretation of the published questionnaire wording and informed by recent systematic reviews, which have synthesised qualitative research examining attitudes towards insulin [15–17].

The questionnaires have considerable overlap but none are identical in item content, and no single questionnaire assesses all themes, or sub-themes, of PIR identified across the measures. All questionnaires include both positively and negatively worded items, although they are generally imbalanced by a strong negative focus. Typically, positive items refer specifically to the positive consequences of insulin therapy (i.e. treatment efficacy) or facilitators of insulin use (i.e. self-efficacy). In contrast, the positively worded items in the BIS (forming the 'functional beliefs' subscale) focus on the acceptance of insulin *despite* negative perceptions of insulin or include double-negative statements stating that insulin would not have a negative impact on the individual. Therefore, the BIS does not assess positive beliefs about insulin therapy. Furthermore, the BIS appears to be conceptually distinct from other PIR questionnaires. Ten BIS items refer to general negative emotional reactions to insulin use, while no other questionnaire includes negatively worded items that cannot otherwise be categorised to a specific concern about insulin use.

Relevance Across Treatment Groups

The ITAS, SHIP and BIS were designed to be suitable for completion regardless of insulin treatment status. To assess differences in PIR between groups, or changes over time, a balance must be struck between the specificity of items (to a treatment type) and applicability (across treatment types). Items that require knowledge or experience of actual insulin therapy may be of limited relevance to those not yet using insulin. This is evidenced by the ITAS item 'insulin causes weight gain', which is one of the only negative items more likely to be endorsed among the those using insulin therapy, compared to those not using insulin [47, 54]. It may be that many people with non-insulin-treated T2D are unaware of the association between insulin therapy and weight gain, and therefore, this issue may not contribute to PIR for them. Similarly, prior to insulin initiation, people with T2D may be unaware of the heightened risk of hypoglycaemia. The BIT two-item fear of hypoglycaemia subscale is preceded by a statement indicating that insulin can lead to 'extremely low blood glucose levels', thus allowing for measurement of concern rather than knowledge. However, such 'scene-setting' does not feature elsewhere in the BIT, or other questionnaires, and likely increases endorsement of these items among those with T2D who may be otherwise unaware of the possibility of experiencing hypoglycaemia as a side effect of insulin. Indeed, this BIT subscale is typically the most highly endorsed negative subscale [46, 56, 66], while, in ITAS studies, several

Table 1 Development history and psychometric properties of five measures of psychological insulin resistance

Name	Barriers to Insulin Treatment Questionnaire (BIT) [46]	Insulin Treatment Appraisal Scale (ITAS) [47]	Study the Hurdles of Insulin Prescription (SHIP) [38]	Beliefs About Insulin Scale (BIS) [50••]	Chinese Attitudes to Starting Insulin Questionnaire (Ch-ASIQ) [48]
Copyright holder (permissions)	Authors: F Petrak et al. (NR)	Novo Nordisk and Prof. F Snoek (NR)	Pfizer. (permission must be sought before use)	Authors: A Gherman (NR)	Authors: SN Fu et al. (NR)
Target population: diabetes type and treatment type[a]	T2D: non-insulin-treated only	T2D: insulin and non-insulin-treated	T1D and T2D: insulin and non-insulin-treated	T2D: insulin and non-insulin-treated	T2D: non-insulin-treated only
Original language (country)	German (Germany)	English (USA)	French (France)	Romanian (Romania)	Chinese (China)
Translations[b]	English version published, which underwent cognitive debriefing [46]	Romanian [32], Chinese for Taiwan and Hong Kong [51, 52] and Turkish [53]. Further psychometric validation in English for Australia [54]	None	English version published [50••], but no assessment of linguistic or psychometric properties	English version published [48] but no assessment of psychometric properties
Number of items	14	20	14	22	13
Response options	10-point scale: completely disagree to completely agree	5-point scale: strongly disagree to strongly agree	4-point scale: this statement applies to me very well/reasonably well/a little/not at all[c]	5-point scale: strongly disagree to strongly agree	4-point scale: totally agree to totally disagree
Questionnaire design informed by:					
Literature review	Yes	Yes			Yes
Clinical experience	Yes	Yes			
Qualitative research with target population (method, n)	Yes (details not reported)		Yes (3 focus groups, n = 23)		
Cognitive debriefing/piloting of items with adults with T2D (method, n)	Yes (English version only, details not reported)		Yes (interviews, n = 16)	Yes (NR, n = 30)	Yes (interviews, n = 10)
Expert panel review			Yes	Yes	Yes
Psychometric testing in original validation sample:					
Validation sample details	Sample 1: N = 448 Sample 2: N = 449 All participants had non-insulin-treaded T2D	N = 282 (48% insulin-treated T2D)	Sample 1: N = 1487 (non-insulin-treated T2D) Sample 2: N = 141 (insulin-treated; T2D = 75.2%)	N = 381 (47.5% insulin-treated T2D)	N = 303
Factor analysis conducted	EFA and item reduction conducted using sample 1, followed by CFA of the final questionnaire in sample 2	EFA conducted using whole sample, not split by treatment type	EFA conducted separately for non-insulin-treated (sample 1) and insulin-treated (sample 2). Each sample was split (ratio = 2:1) to	EFA conducted using whole sample, not split by treatment type	EFA conducted on whole sample

Table 1 (continued)

Name	Barriers to Insulin Treatment Questionnaire (BIT) [46]	Insulin Treatment Appraisal Scale (ITAS) [47]	Study the Hurdles of Insulin Prescription (SHIP) [38]	Beliefs About Insulin Scale (BIS) [50••]	Chinese Attitudes to Starting Insulin Questionnaire (Ch-ASIQ) [48]
			form (a) an EFA and item reduction subset and (b) a subsequent EFA and validation dataset using the proposed items for the final questionnaire		
Final questionnaire structure	Single factor: Total score: 14 items (loadings not reported) Multi-dimensional factor structure 1. 'fear of injection and self-testing': 3 items 2. 'Expectations regarding positive insulin-related outcomes': 3 items 3. 'Expected hardship from insulin treatment': 3 items 4. 'Stigmatisation by insulin injections': 3 items 5. 'Fear of hypoglycaemia': 2 items (items loaded ≥0.4 on relevant factors)	Single factor: Total score: 20 items (loading not reported, low commonalities for 5 of 20 items). Multi-dimensional factor structure: 1. 'Positive subscale': 4 items. (items loaded ≥0.4) 2. 'Negative subscale': 16 items (15/16 items loaded ≥0.4)	Single factor: NR multi-dimensional factor structure: 1. 'Acceptance and motivation': 5 items 2. 'Fears and constraints': 5 items 3. 'Restrains and barriers': 4 items (Items loaded ≥0.4 on relevant factors)	Single factor: NR multi-dimensional factor structure: 1. 'Dysfunctional beliefs': 14 items. (13/14 items loaded ≥0.4). 2. 'Functional beliefs': 8 items. (7/8 items loaded ≥0.4)	Single factor: NR multi-dimensional factor structure: 1. 'Self-image and stigmatisation': 3 items 2. 'Factors promoting self-efficacy': 5 items 3. 'Fear of pain or needles': 3 items 4. 'Time and family support': 2 items (items loaded ≥0.4 on relevant factors)
Scoring	Mean of scores. Range: 1–10	Sum items. For total score, positive items reversed. Total scale range: 20–100 1. Range: 4 to 20 2. Range: 16 to 86	Sum items, standardise out of 100	Sum items. 1. Range: 0–56 2. Range: 0–32	NR Subsequent study: mean of items, range: 1–4 [55]
Internal consistency (Cronbach's alpha)	Sample 2. Total α = 0.78 1. α = 0.85 2. α = 0.66 3. α = 0.81 4. α = 0.62 5. α = 0.78	Total α = 0.89 1. α = 0.90 2. α = 0.68	Sample 1–sample 2: 1. α = 0.82–0.81 2. α = 0.77–0.79 3. α = 0.78–0.74	1. α = 0.87 2. α = 0.67	1. α = 0.80 2. α = 0.68 3. α = 0.65 4. α = 0.62
Test-retest reliability	NR	NR Subsequent study: reported for Chinese-ITAS items, r range = 0.294–0.725 [51]	NR	NR	NR
Convergent validity[d]	NR	Assessed: diabetes distress (Problem Areas in Diabetes; PAID) and	Assessed: diabetes fear of injecting and self-testing questionnaire. Moderate	Assessed: PIR (ITAS) and general belief	NR

Table 1 (continued)

Name	Barriers to Insulin Treatment Questionnaire (BIT) [46]	Insulin Treatment Appraisal Scale (ITAS) [47]	Study the Hurdles of Insulin Prescription (SHIP) [38]	Beliefs About Insulin Scale (BIS) [50••]	Chinese Attitudes to Starting Insulin Questionnaire (Ch-ASIQ) [48]
		general emotional wellbeing (WHO-5) WEAK significant correlations observed across total and subscale scores (PAID: *r* range = ±0.21–0.35; WHO-5: *r* range = ±0.12–0.14)	correlations observed for 2/3 domains: 1. $r = -0.18$ 2. $r = 0.41$ 3. $r = 0.42$	measures (Attitudes and Beliefs Scale; Survey of Personal beliefs; Automatic thoughts Questionnaire) Large correlation observed between Dysfunctional Beliefs and ITAS negative scores ($r = 0.71$, $p < 0.05$), and moderate correlation between Functional Beliefs with two Attitudes and Beliefs Scale subscales (r range = 0.40–0.43, $p < 0.05$)	
Known-groups validity[e] (non-insulin using vs. insulin-using)	N/ASubsequent studies: confirmed for total and 3/5 subscale scores (not confirmed for: 'positive insulin-related outcomes' and 'fear of hypoglycaemia' [56]	Confirmed for total ($p < 0.001$) Negative ($p < 0.001$) and positive ($p < 0.05$) scores. Confirmed for 19/20 item scores ($p < 0.05$) Subsequent studies: confirmed for negative subscale, but inconsistent confirmation for positive subscale [54, 56–58]	NR	Dysfunctional beliefs: confirmed ($p < 0.001$, $d = 0.66$). Functional beliefs: NR	N/A
Concurrent validity[f] (hypothetical willingness to initiate/intensify)	Confirmed for total score ($p < 0.001$, $d = 0.76$) and subscales scores ($p < 0.01$, d range: 0.35–0.66) Subsequent studies: further confirmation [59]	NR Subsequent studies: confirmed for total score [36, 37] and subscales [31]	Insulin initiation (sample 1): confirmed for all domains. Insulin intensification (sample 2): confirmed for domains 1 and 2	NR	NR
Predictive validity[g] (insulin initiation/intensification)	NR Subsequent studies: total score associated with time until insulin initiation [60]	NR Subsequent studies: baseline subscales significantly associated with use at 12 months uptake [31, 39••]	Insulin initiation (sample 1): confirmed for domains 1 and 2. Insulin intensification (sample 2): not supported for any domain	NR	NR
Responsiveness[h]	NR. Subsequent studies:	NR	NR	NR	NR

Table 1 (continued)

Name	Barriers to Insulin Treatment Questionnaire (BIT) [46]	Insulin Treatment Appraisal Scale (ITAS) [47]	Study the Hurdles of Insulin Prescription (SHIP) [38]	Beliefs About Insulin Scale (BIS) [50••]	Chinese Attitudes to Starting Insulin Questionnaire (Ch-ASIQ) [48]
	following change to insulin delivery device: one study reported moderate-to-large change in total and subscale scores following insulin delivery device intervention [61•]	Subsequent studies:following insulin initiation: two studies reported significant change in negative scores, but not positive scores [39••, 58]; one study reported change in total and both subscale scores [62]. Following change to insulin delivery device: one study reported moderate change in total and negative score, and small change in positive scores [61•]			
Completion time	NR	NR	NR	10–15 min	NR
Readability (e.g. Flesch reading ease)	NR	NR	NR	NR	NR
Number of empirical studies using this measures[i]	6	15	0	0	1

α Cronbach's alpha, *CFA* confirmatory factor analysis, *EFA* exploratory factor analysis, *NR* not reported, *T1D* type 1 diabetes, *T2D* type 2 diabetes

[a] Questionnaires are equivalent between treatment groups, but slight terminology differences are used in the BIS and SHIP to reflect current treatment

[b] Translations may or may not have been validated culturally, linguistically or psychometrically; based upon information available when this review was submitted. Readers are advised to contact copyright holder(s) for current language(s) available

[c] SHIP response options not reported. English translation provided by authors

[d] Convergent validity is confirmed if the correlation between measures hypothesised to be related to each other is at least moderate ($r \geq 0.4$)

[e] Known-groups, or extreme groups, validity is confirmed if scores significantly differ between two groups which would be expected to differ (e.g. non-insulin treated vs. insulin-treated) in respect of the construct

[f] Concurrent validity is confirmed if the measure significantly differentiates hypothetical willingness to initiate/intensify insulin therapy.

[g] Predictive validity is confirmed if the measure is a significant predictor of future insulin uptake or intensification

[h] Responsiveness is confirmed if the measure is sensitive to change (i.e. change in treatment or other intervention)

[i] Number of studies published in English language (beyond validation study) reporting use of measure, including cross-sectional, longitudinal and translation studies. Search involved inspecting citations of questionnaire development and validation articles as captured by Scopus (February 2017)

other negative insulin appraisals are more commonly endorsed than concern about hypoglycaemia among people with non-insulin-treated T2D [47, 54].

Qualitative studies suggest people with insulin-treated T2D perceive multiple daily injections (i.e. >3) and quick-acting insulins as less convenient and indicating worse health than less intensive insulin regimens [23•], potentially contributing to resistance to further treatment intensification. Concerns about self-titrating insulin doses are discussed elsewhere [24••]. However, negative attitudes to specific insulin regimens, insulin intensification or self-titration are not incorporated in the ITAS or BIS, and therefore, these measures may have limited sensitivity in differentiating negative attitudes to insulin intensification, or types of insulin therapy. In contrast, the SHIP includes an item referring specifically to concern that insulin treatment may become more complicated over time and refers specifically to either insulin 'initiation' or 'intensification' depending on the respondents' current treatment regimen. However, due to the SHIP's focus on attitudes towards treatment progression, this measure cannot be used to assess change in attitudes towards insulin in general.

Psychometric Properties

Table 1 details the psychometric validation process employed for each questionnaire, the number of items and subscales in the final questionnaire as well as the reliability, validity and responsiveness of each questionnaire.

All questionnaires were subject to exploratory factor analysis (EFA) to assess scale structure and identify potential items for removal. The SHIP and BIT were subject to the most robust psychometric testing process, including initial factor analysis and item reduction in one dataset, followed by further factor analysis of the final questionnaire and validation testing in a second dataset. Only the BIT was subject to confirmatory factor analysis following questionnaire finalisation. Despite the relatively rigorous approach taken to develop the Ch-ASIQ item pool (see Table 1), less attention was paid to item reduction and examination of scale structure. Following an unforced factor analysis, items were dropped based on single-factor loadings, factors were then manually collapsed (not informed EFA), and dropped where internal consistency was deemed inadequate ($\alpha < 0.6$). Inspection of eigenvalues suggests a forced three-factor structure warrants investigation (based on the knick-criterion). Further psychometric testing of the Ch-ASIQ should include an iterative item reduction and factor analysis approach.

Multi-dimensional scale structures were reported of all questionnaires (see Table 1). The BIT and the Ch-ASIQ subscales each relate to a specific aspect of PIR (or facilitator of insulin use), such as injection-related anxieties). In contrast, the ITAS and the BIS each encompass just two dimensions including either positive or negative statements about insulin therapy. The SHIP includes one dimension focused around positive expectations and facilitators of insulin use, but concerns about insulin are split across two dimensions. An underlying single-factor structure was investigated for the BIT and ITAS, and total scores have been recommended for use. More recent research has replicated the two-factor structure of the ITAS, but discouraged the use of the total score [54].

For questionnaires suitable for use regardless of insulin treatment, psychometric properties need to be considered separately by treatment group (insulin-treated and non-insulin-treated). Separate EFA was undertaken by treatment group for the SHIP, but was not reported for the BIS. Original validation of the ITAS did not include separate EFA by treatment group [47] but this has been conducted subsequently and found to be satisfactory [54]. It is of note, however, that the entire ITAS scale was more commonly skipped by participants not using insulin compared to those insulin treated (7 vs. 0%) [54], suggesting this group may have questioned the relevance of the ITAS to their experience. Future researchers using the ITAS with non-insulin-treated populations might consider modifying the instructions to emphasise the questionnaire's relevance and maximise completion rates.

Known-Groups Validity

It is expected that the experience of PIR differs (qualitatively and quantitatively) between those with insulin and non-insulin-treated T2D, and therefore, PIR questionnaire scores should differ between groups. ITAS total and subscale scores were found to differ significantly by treatment group, whereby greater, more negative, scores were reported among those not using insulin therapy [47]. In subsequent research, inconsistent results have been demonstrated for the ITAS positive score [54, 56–58]. BIS dysfunctional beliefs scores were significantly higher among those with non-insulin-treated T2D who had refused insulin treatment compared to those who were currently using insulin. Despite not being developed for use beyond insulin initiation, BIT total and subscale scores differentiated treatment groups (insulin versus non-insulin), with the exception of the 'positive insulin-related outcomes' and 'fear of hypoglycaemia' subscales [56]. Post-insulin initiation, the SHIP measures attitudes towards insulin intensification, not insulin in general, and therefore, direct comparisons have not be made between treatment groups.

Predictive and Concurrent Validity

PIR is not a clinical diagnosis and thus defining a cut-point on PIR questionnaires is neither necessary nor appropriate. However, given the clinical importance of timely treatment intensification, it is important to establish the utility of PIR questionnaires in predicting actual insulin uptake or intensification (predictive validity) or discriminating between those

hypothetically willing and unwilling to commence insulin therapy (concurrent validity). A significant association between hypothetical willingness to begin insulin and attitudes towards insulin was demonstrated in the original validation of the BIT and SHIP [38, 46], and more recently for the BIT [59] and the ITAS [31]. Furthermore, two SHIP domain scores ('acceptance and motivation' and 'constraints and fears') were found to predict willingness to intensify insulin among people with insulin-treated diabetes.

The predictive validity of the SHIP was examined with regard to actual insulin initiation and intensification. Two of the three domains ('acceptance and motivation' and 'constraints and fears') adequately predicted insulin initiation, but none were predictive of intensification of insulin. Recently, prospective research has demonstrated that ITAS negative and positive scores contribute significantly to the prediction of insulin uptake [39••], and more negative BIT total scores among adults with newly diagnosed T2D are associated with a longer time to insulin initiation [60].

Sensitivity to Change

Longitudinal research has demonstrated significant improvements in ITAS total and negative scores following insulin initiation, but inconsistent change in ITAS positive scores [39••, 58, 62]. No prospective research has examined change in BIS or SHIP scores following insulin initiation or intensification. The responsiveness of the ITAS and BIT to change in insulin administration (from insulin injections to novel patch-on insulin delivery) was examined in a small ($N = 18$), 2-week single-arm study [61•]. Strong significant change in BIT total scores was observed and non-significant changes, with a moderate effect size, were observed for ITAS scores. Given the apparent responsiveness of the BIT among those using insulin therapy, further research may be warranted in this population.

Practical Considerations

In addition to the conceptual focus, development rigour and psychometric properties, researchers/clinicians need also to consider questionnaire characteristics that affect access and use, e.g. length, language availability, readability and ease of scoring (see Table 1). All five PIR questionnaires discussed here are relatively brief (range 13 to 22 items) and may be completed in a few minutes. Questionnaire scoring is not onerous, involving either computing a sum or mean of item responses. The ITAS is the most widely translated questionnaire, having been developed in English [47] and subsequently translated for use in Turkish [53], Romanian [32] and Chinese [51, 52] populations. However, translations may not have been subject to linguistic or psychometric validation, and the ITAS two-dimensional scale structure was not supported within a Hong Kong sample [51]. English translations (involving forward/backward translation and review) are available for the BIT [46], originally developed in German, and the Ch-ASIQ [48]. A direct English translation of the Romanian BIS and an English summary version of the French SHIP are published, but full cultural and linguistic validation has not been conducted. Beyond translation, the cultural appropriateness of a scale needs also to be considered. Thus, while the ITAS has a strong development and validation history and is recommended for most applications, the attitudes towards insulin assessed may not comprehensively represent the experience of PIR in non-western countries or cultural groups [48].

Choice of measure may also be influenced by the frequency of prior use, which may provide a context for research extension and cross-study comparisons. The ITAS is the most commonly used PIR questionnaire in published empirical research to date, followed by the BIT (see Table 1). Despite being published in the same year as the ITAS and BIT, the SHIP has not been used subsequently in published research to our knowledge.

Directions for Future Research

Following critical review of the available validated PIR measures, directions for future research and scale improvement are apparent. Positive attitudes towards insulin use are associated with intention to begin insulin therapy [38, 46], independent of negative attitudes [31]. This is consistent with the recent proposition of the utility of the 'necessity-concerns framework' in understanding the decision-making process to initiate insulin therapy [40••]. However, across PIR questionnaires, few items assess positive perceptions of insulin therapy, relative to negative attitudes. For example, the ITAS includes four positive items, compared to 16 negative items. Furthermore, positive items commonly refer to knowledge of physiological benefits (e.g. ITAS: 'maintain good control of blood glucose', BIT: 'prevent long-term complications'), which could be applied to any pharmacological treatment of diabetes, rather than to the consequences of insulin specifically. Qualitative studies have identified other, more specific, benefits of insulin therapy, including increased dietary flexibility due to the ability to adjust insulin (assessed in the SHIP), feeling more positive about health in general, relief over the ease of using insulin devices/injecting and insulin use fostering personal control over diabetes [23•, 67, 68]. PIR questionnaires may benefit from revision, with the development and testing of new positive items referring to additional, and perhaps more immediately salient, benefits. Additional items may also improve the ability of positive subscales to discriminate between treatment groups [54, 56, 58] and the responsiveness of positive subscales [39••, 58, 61•].

The impact of PIR beyond insulin initiation has received little research attention. No research has examined the association between PIR and insulin omission using validated questionnaires and a recent review article called for further research to examine the relationship between PIR and intensification of insulin [69]. The SHIP was designed specifically to assess barriers to insulin intensification (in addition to initiation), but the predictive validity of this measure with regard to insulin intensification was not supported, and little research has since examined the relationship between PIR and insulin intensification. PIR questionnaires may not adequately assess concerns about specific insulin regimens and types of insulin, which have been identified in qualitative literature [23•, 41]. Research is warranted to investigate, and optimise, the predictive validity of PIR measures in relation to optimal insulin-taking behaviours and insulin intensification.

Finally, the responsiveness of BIT and ITAS has been demonstrated following change in diabetes treatment [39••, 58, 61•]. However, the sensitivity of scales in response to intervention aimed to reduce PIR or clinical counselling is unknown, as few interventions have been designed to reduce PIR [70, 71], and their impact has not been evaluated using validated PIR measures. Furthermore, PIR questionnaires may provide a foundation for the future development of tailored PIR interventions. This is an area for future research.

Implications for Clinical Practice

Research suggests that HCPs have pre-conceived ideas about the willingness of people with non-insulin-treated T2D to begin insulin therapy and anticipate negative emotional reactions [12, 72, 73]. In clinical practice, the question of willingness to begin insulin may be perceived as confrontational and blunt by the person with T2D, whose negative response may then discourage the HCP in the timely initiation of insulin therapy. In contrast, exploring attitudes towards insulin use may assist HCPs in providing practical support to increase receptiveness to insulin therapy (i.e. education, problem-solving, practical skills) and assist the person with T2D to make an informed treatment decision. A practical guide on how to have such an open-ended discussion about PIR has been described elsewhere [74•].

The completion of a relatively brief PIR questionnaire within or prior to the consultation may help to identify the most salient barriers and guide discussion. Alternatively, where the possibility of questionnaire completion is limited by consultation times, language availability or literacy skills, HCPs might choose to use PIR questionnaires as a checklist to guide clinical discussions around insulin therapy. The BIS was designed specifically, but not yet tested, to identify beliefs that may be addressed clinically using empirically validated cognitive-behavioural strategies. Other PIR measures identify practical barriers to insulin use, which would be more easily addressed within clinical care, rather than requiring psychological intervention. The ITAS has a strong development and validation history and is widely used and has the advantage over many other PIR measures of being suitable for use before and after insulin initiation. However, HCPs should be mindful that the use of any single PIR questionnaire within care may limit discussion to the barriers included in that specific measure. As shown in Appendix 1, no questionnaire is inclusive of all identified aspects of PIR across questionnaires, and still other barriers to insulin use may exist.

Conclusion

PIR has been defined and operationalised in terms of psychological barriers to insulin use among people with T2D, which may lead to refusal of insulin initiation or intensification. The measurement of actual or hypothetical insulin refusal offers insight into the extent of one potential impact of PIR, but ignores factors that may prevent or encourage insulin use. Furthermore, focusing on willingness to initiate/intensity insulin overlooks the potential impact of ongoing concerns about insulin therapy on daily self-care behaviours. For this reason, it is recommended that PIR measurement focuses on exploring attitudes to insulin therapy rather than simply on insulin refusal. In this review, six validated measures of PIR were identified, five of which are published in English-language, peer-reviewed journals. Choice of measures needs to be guided by the clinical or research aim, taking into consideration the sample (i.e. linguistic and cultural validity), clinical time point (i.e. identifying barriers to insulin initiation, ongoing use, or intensification) and the contextual face validity of PIR questionnaires relative to clinical/research interest, in addition to the psychometric strengths and limitations described above. For most clinical and research applications in Western countries, the ITAS appears to have the strongest basis for recommendation. As well as barriers, perceived benefits or facilitators of insulin therapy are associated independently with intention to begin/intensify insulin therapy and may warrant more comprehensive assessment (for example, only 4/20 ITAS items are positive). The development and testing of additional positive items is indicated by qualitative research findings. Further research is needed to assess the clinical utility of PIR questionnaires to assist HCPs in identifying and addressing perceived barriers of insulin therapy, as well as the responsiveness of these questionnaires to clinical intervention.

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Compliance with Ethical Standards

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- • Of importance
- •• Of major importance

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