Assessing barriers to insulin therapy among people with type 2 diabetes in South Africa using the Insulin Treatment Appraisal Scale: a cross-sectional survey

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Highlights

- The Insulin Appraisal Treatment Scale (ITAS) has not been used to assess barriers to insulin therapy in South Africans living with diabetes.
- An expert panel found that the ITAS is relevant to the South African context.
- Insulin-naïve participants held more negative beliefs towards insulin than those who were on insulin.

- The negative attitudes of non-insulin users were related to injection-related anxieties including fear of injection and pain.

ABSTRACT

Aims: To assess barriers to insulin therapy among people with type 2 diabetes after adapting the Insulin Treatment Appraisal Scale (ITAS) to the South African context.

Methods: A panel of experts reviewed the original ITAS for clarity and relevance to the South African context. The ITAS was administered to 253 adults with type 2 diabetes attending diabetes outpatient clinics in the Tshwane Metropolitan Municipality. Internal consistency (Cronbach's alpha) was tested and construct validity was examined using exploratory factor analysis (EFA). PIR was appraised in insulin users and non-users.

Results: The EFA revealed that the adapted ITAS had a two-factor structure, similar to the original scale, with acceptable internal consistency ($\alpha = 0.85$). Insulin-using participants had significantly less negative attitudes to insulin therapy than non-users (40.7 ± 7.1 vs. 51.5 ± 11.2, $p < 0.001$). Compared to participants who used insulin, participants who did not use insulin were afraid of injecting themselves with a needle (71% vs. 11%, $p < 0.001$) and saw insulin treatment as a sign of worsening diabetes (63% vs. 29%, $p < 0.001$).

Conclusions: Consistent with previous studies, participants who were not using insulin had more negative beliefs and attitudes towards insulin treatment than those who were already using insulin. South African clinicians should use the ITAS to assess positive and negative perceptions regarding insulin therapy in both insulin-naïve and insulin-treated people, to evaluate interventions to reduce PIR and improve treatment outcomes.

Keywords: Type 2 diabetes; Insulin therapy; Insulin Treatment Appraisal Scale; Psychological Insulin Resistance.

1. Introduction

Type 2 diabetes mellitus is a progressive disease and most people on oral glucose-lowering agents will require insulin therapy within five to ten years of diagnosis [1]. Despite robust evidence of the benefits of early strict glucose control, there is often a delay in insulin initiation and titration [2]. Delayed initiation of insulin therapy may be due to patient factors such as fear of injections, concerns about side effects (e.g. hypoglycaemia and weight gain), and misconceptions about insulin [3]. Patients' beliefs and attitudes have been implicated in being important barriers to insulin therapy [4]. Negative attitudes towards insulin therapy have been collectively termed "psychological insulin resistance (PIR)" [5]. Psychological insulin resistance is described as psychological barriers (cognitive, emotional, relational and cultural) to insulin use among people with type 2 diabetes, which may lead to refusal of insulin initiation or intensification [6].

In South Africa, type 2 diabetes and its complications are a concerning source of morbidity and mortality [7]. Given the levels of suboptimal glycaemic control in South Africa [8-10], assessing the contributors to suboptimal control including PIR coupled with targeted interventions may improve patient care and outcomes. Indeed, previous studies in South Africa and elsewhere have linked poor glycaemic control to lack of intensification of therapy in insulin-requiring patients [5, 11, 12]. In South Africa, previous studies have identified PIR in people with type 2 diabetes [13, 14]. These studies assessed PIR using non-validated questionnaires instead of using internationally recognised instruments such as the "Insulin Treatment Appraisal Scale" (ITAS) [15], the "Barriers to Insulin Treatment" (BIT) [16], or the "Chinese Attitudes to Starting Insulin Questionnaire" (Ch-ASIQ) [17]. Consequently, using non-validated questionnaires to measure PIR in South African people with type 2 diabetes limits comparison between studies.

In South Africa, Nadasen et al. [13] explored the reasons behind a perceived reluctance of people with uncontrolled type 2 diabetes to commence insulin therapy despite objective evidence for augmenting oral treatment with insulin. Most patients refused insulin therapy because they were afraid of injections and needles[13]. Another study assessed the factors associated with willingness to start insulin among people with type 2 diabetes in primary care and found that most participants were unwilling to accept insulin therapy if recommended by a doctor [14]. The common reasons for patient unwillingness were injection anxieties, fear of

needles, insufficient knowledge of insulin, low self-efficacy and concerns about out-of-pocket costs [14].

In this study, we sought to assess the barriers to insulin therapy amongst South African people with type 2 diabetes using an internationally recognised instrument. We chose the ITAS because it is the most commonly used PIR questionnaire. Contrary to other measures, ITAS can be used before and after insulin initiation, and has been translated into various languages including Turkish, Romanian and Chinese [6]. The original ITAS was developed and validated in the United States to identify the reasons for PIR amongst people with diabetes, to assess positive and negative perceptions regarding insulin and to aid in patient education and counselling [15].

After adapting the ITAS to the South African context, we assessed the barriers to insulin therapy in a large sample of people with type 2 diabetes, both using and not-using insulin, and attending public healthcare facilities.

2. Participants and methods

This cross-sectional study was conducted over three months between June and August 2019 in the City of Tshwane Metropolitan Municipality, situated in the northern part of Gauteng Province in South Africa. The study included research sites from various levels of care namely primary, secondary and tertiary healthcare. These research sites represent the Tshwane Insulin Project (TIP), a 5-year translational research programme aiming to optimise insulin use for people with type 2 diabetes in South Africa [18].

The study was approved by the Research Ethics Committee of the Faculty of Health Sciences of the University of Pretoria (Reference No.: 285/2019) and the Tshwane Research Council (No: GP_201810_049), and adhered to the Declaration of Helsinki. Written informed consent was obtained from all participants before collecting data.

2.1. Adaptation of the ITAS

A panel of ten South African experts reviewed the original ITAS and assessed each item for content, appropriateness and relevance to the South African context. The panel comprised of two diabetes specialist physicians, two professional nurses from a tertiary diabetes clinic and

four research assistants experienced in diabetes research. For each item, an interrater agreement score between 0.7 and 0.8 was deemed acceptable [19]. Then, the researchers (JWM, EMW and PNP) plus two representatives from the expert panel reworded the original ITAS based on the panel's recommendations. The researchers made minor changes to the tool to make it understandable in the local context [20]. We recruited 15 adults at a tertiary diabetes clinic who have type 2 diabetes and are fluent in English. The adapted ITAS was pre-tested amongst these patients to assess clarity. Lastly, we analysed the reliability of the adapted tool, as well as its construct and discriminant validity.

2.2. Sample selection

Fieldworkers recruited participants from five primary care clinics, one secondary hospital and two tertiary academic hospitals in Tshwane. At least 200 participants were required based on the recommended ratio of items to participants, 1:10 [21]. For practical reasons, people with type 2 diabetes attending routine visits were invited to participate in the study if they were 18 years or older and able to give written informed consent.

2.3. Measuring PIR using the ITAS

Trained fieldworkers who were fluent in local languages were trained to administer the ITAS. Their training was focused on the survey instrument and the concepts that the questions were trying to assess. The fieldworkers were able to assist illiterate participants or those who were unable to understand the questionnaire. The ITAS was used to measure PIR. Respondents indicated their level of agreement on a 5-point Likert scale from 'strongly disagree' = 1 to 'strongly agree' = 5. Scores for the 16 negatively-worded items were summed to provide a 'negative appraisal' score (16 – 80); scores for the 4 positively-worded items were summed to provide a 'positive appraisal' score (4 – 20); all twenty items were summed (with positively-worded items reversed) to give a 'total' score ranging between 20 and 100. Higher 'total' and 'negative appraisal' scores indicate more negative attitudes, while higher 'positive appraisal' scores indicate more positive attitudes towards insulin therapy [22].

2.4. Participants' demographic and clinical information

Demographic information (sex, age, ethnicity, level of education, duration of diabetes, employment and marital status) and clinical information (diabetes medication, HbA_{1C}) were collected during interviews with participants and from medical records.

2.5. Data analysis

Data were analysed using Stata version 15.1 (Statacorp LP, Texas, USA). The reliability of the scale was assessed using Cronbach's alpha for internal consistency where a value ≥ 0.70 and < 0.90 was considered reasonable. The construct validity of the tool was analysed using exploratory factor analysis (EFA) using principal axis factoring and promax oblique rotation because the factors were correlated [23]. We tested the adequacy of the sample using the Kaiser–Meyer–Olkin (KMO) value and justified the factor analysis using Bartlett's test. The maximum number of factors was determined by assessing the scree plot using the Kaiser-criterion (Eigenvalue > 1). Item loadings were considered optimal if they were > 0.40 on one factor and < 0.30 on any other factor [15]. Discriminant validity was assessed by comparing total ITAS, negative and positive scores between insulin users and non-users.

Descriptive statistics were used to calculate frequencies, means ± standard deviations or medians as appropriate following normality testing. Differences in demographic, HbA_{1C} levels and ITAS scores between insulin users and non-users were compared using chi-squared tests for categorical data and the Student's t-test or the Mann-Whitney U test for continuous data. Effect sizes are reported using Cohen's d .where ≤ 0.2 represents a 'small' effect size, 0.3 – 0.5 is considered a 'medium' effect size and ≥ 0.8 a 'large' effect [24]. Statistical significance was set at $p < 0.05$.

3. Results

3.1. Adaptation of the tool

The expert panel agreed that all the items of the ITAS were relevant (interrater mean agreement score ≥ 0.8). For content and appropriateness, four items (1, 5, 12 and 20) had low mean agreement scores < 0.7. These items were reworded to improve clarity. For item 1: "manage" was replaced with "control"; item 5: "less flexible" was replaced with "more difficult"; item 12: "deteriorate" was replaced with "get worse" and item 20: "makes me more dependent on the doctor" was replaced with "I have to see the nurse/doctor more often". In addition, "nurse" was added to all the items that referred to a doctor, because nurses conduct most consultations with patients in primary care in South Africa [25]. Similarly, the term "blood glucose" was replaced with "blood sugar" since the latter is commonly used by people with type 2 diabetes. The pre-test of the ITAS showed that participants understood all items of the questionnaire.

Table 1: Exploratory factor analysis (EFA) for the 20 items of the adapted Insulin Treatment Appraisal Scale: Forced two-factor solution after Oblimin rotation.

Item #	Item content	Factor loadings	
		Factor 1	Factor 2
1	Taking insulin means I have failed to manage my diabetes with diet and tablets	0.397	
2	Taking insulin means my diabetes has become much worse	0.498	
3	Taking insulin helps to prevent complications of diabetes		0.727
4	Taking insulin means other people see me as a sicker person	0.512	
5	Taking insulin makes life more difficult	0.446	0.310
6	I'm afraid of injecting myself with a needle	0.521	
7	Taking insulin increases the risk of low blood sugar levels (hypoglycemia)	0.437	
8	Taking insulin helps to improve my health		0.617
9	Insulin causes weight gain	0.471	
10	Managing insulin injections takes a lot of time and energy	0.632	
11	Taking insulin means I have to give up activities I enjoy	0.648	
12	Taking insulin means my health will get worse	0.593	
13	Taking insulin is embarrassing	0.500	
14	Injecting insulin is painful	0.602	
15	It is difficult to inject the right amount of insulin correctly at the right time every day	0.495	
16	Taking insulin makes it more difficult to fulfill my responsibilities (at work, at home)	0.700	
17	Taking insulin helps to maintain good control of my blood sugar		0.664
18	Being on insulin causes family and friends to be more concerned about me	0.460	-0.343
19	Taking insulin helps to improve my energy levels		0.756
20	Taking insulin means I have to see the nurse/doctor more often	0.607	

The minor changes made to the ITAS did not affect its reliability. Cronbach's alpha was 0.85 for the 20-item ITAS scale, 0.84 for the 16 negative items and 0.68 for the 4 positive items demonstrating satisfactory homogeneity. The KMO value of 0.83 and significant Barlett test ($p < 0.001$) indicated suitability for EFA. The EFA revealed four factors with an Eigenvalue >1 explaining 51% of the total variance. The "knick" in the scree plot suggested a two; three or four factor structure. The one-, two-, three- and four-factor solutions were generated by principle component factoring with Oblimin oblique rotation. The one-, three- and four-factor solutions were unsuitable either due to ≥ 3 items not loading adequately (factors 1 and 3) or being difficult to interpret (factor 4). In the two-factor solution, 15 negative items loaded onto one factor with the remaining negative statement (item 1) "failed on insulin therapy" not

loading adequately while the four positive items loaded to the second factor. Only item 5 (makes life more difficult) and item 18 (family and friends to be more concerned) loaded > 0.3 on more than one factor. The two-factor solution was the easiest to interpret and best represented the inherent structure of the original ITAS (Table 1).

3.2. Participant characteristics

Demographic and clinical characteristics are recorded in Table 2. Most of the participants (N = 253) were women (60%), had reached secondary school (62%), were married (53%), received diabetes care at hospital level (57%) and were using insulin (53%) with a mean age of 57.9 ± 11.6 years. In this sample, insulin users received care in hospital (78% vs. 36%, p <0.001) and had diabetes for longer than non-insulin users (12.0 vs. 5.0 years, p <0.001). Non-insulin users appeared to have better glycaemic control compared to insulin users (8.6% vs 9.4%, $p = 0.047$).

3.3. Appraisal of insulin therapy using the ITAS

The responses to the 20-item ITAS questions are reported in Table 3. Participants who did not use insulin had higher ITAS scores compared to insulin-treated participants (61.4 ± 12.4 vs. 48.6 ± 8.0, $d = 1.24$, $p < 0.001$).

Negative scale scores were significantly higher in non-insulin users compared to insulin users (51.5 ± 11.2 vs. 40.7 ± 7.1, $d = 1.17$, $P < 0.001$). Non-insulin using participants were more afraid of injecting themselves with a needle (71% vs. 11%, $d = 1.47$), they were more convinced that insulin makes life more difficult (58% vs. 24%, $d = 0.77$), and they believed that injecting insulin is painful (49% vs. 19%, $d = 1.03$). Non-insulin users felt that taking insulin signalled an inability to control diabetes with diet and tablets (54% vs. 36%, $d = 0.46$) and as a sign of worsening diabetes (63% vs. 29%, $d = 0.83$) compared to users.

Insulin users had significantly higher positive ITAS scores (16.1 ± 2.2 vs. 14.0 ± 3.0, $d = -0.80$, $p < 0.001$) compared to non-insulin users, suggesting more positive attitudes towards insulin therapy. Insulin users were more likely to indicate that insulin helps to maintain good sugar control (92% vs. 68%, $d = -0.38$), improves health (90% vs. 50%, $d = -0.79$), improves energy levels (81% vs. 49%, $d = -0.56$) and prevents complications (77% vs. 55%, $d = -0.37$). More insulin users indicated that being on insulin caused family and friends to be more concerned (75% vs. 66%, $d = -0.09$).

Table 2: Socio-demographic and clinical characteristics of the study participants (N = 253) by insulin use.

Patient characteristics	Total	Insulin naïve (N=120)	Insulin treated (N=133)	*p*-value*
Sex, N (%)				
Women	152 (60%)	74 (62%)	78 (59%)	0.624
Men	101 (40%)	46 (38%)	55 (41%)	
Age (years), mean ± SD	57.9 ± 11.6	58.7 ± 12.3	57.1 ± 11.0	0.250
Race, N (%)				
African	177 (70%)	77 (64%)	100 (76%)	0.132
White	39 (16%)	24 (20%)	15 (11%)	
Coloured	18 (7.1%)	8 (6.7%)	10 (7.6%)	
Asian/Indian	18 (7.1%)	11 (9.2%)	7 (5.3%)	
Educational attainment, N (%)				
Primary school	70 (28%)	35 (29%)	35 (26%)	0.463
Secondary school	157 (62%)	70 (58%)	87 (65%)	
Tertiary education	21 (8.3%)	13 (11%)	8 (6.0%)	
No schooling	5 (2.0%)	2 (1.7%)	3 (2.3%)	
Employment status, N (%)				
Employed	90 (36%)	43 (36%)	47 (35%)	0.793
Unemployed	78 (31%)	39 (33%)	39 (29%)	
Retired	85 (34%)	38 (32%)	47 (35%)	
Marital status, N (%)				
Divorced	38 (15%)	20 (17%)	18 (14%)	0.913
Married	134 (53%)	61 (51%)	73 (55%)	
Never married	47 (19%)	21 (18%)	26 (20%)	
Separated	8 (3.2%)	4 (3.4%)	4 (3.0%)	
Widowed	25 (9.9%)	13 (11%)	12 (9.0%)	
Level of care, N (%)				
Primary care	108 (43%)	77 (64%)	31 (23%)	<0.001
Hospital level (secondary and tertiary)	145 (57%)	43 (36%)	102 (77%)	
Diabetes duration (years), median (IQR)	9.0 [3.0, 15.0]	5.0 [1.0, 10.0]	12.0 [6.0, 19.0]	<0.001
HbA1C, mean ±SD (%)	9.0 ± 2.9	8.6 ± 3.2	9.4 ± 2.7	0.047

*Comparison between non-insulin using and insulin using participants. SD, standard deviation; IQR, interquartile range

Table 3: Differences in ITAS mean scores per item, sub-scale and total scores and effect sizes for the adapted Insulin Treatment Appraisal Score (ITAS) by insulin use.

	Non-insulin users		Insulin users		
	Mean ± SD	**A/SA (%)**	**Mean ± SD**	**A/SA (%)**	***d***
1. Taking insulin means I have failed to control my diabetes with diet and tablets.	3.4 ± 1.3	54%	2.8 ± 1.2**	36%***	0.46
2. Taking insulin means my diabetes has become much worse.	3.6 ± 1.2	63%	2.6 ± 1.1**	29%**	0.83
^3. Taking insulin helps to prevent complications of diabetes.	3.4 ± 1.2	55%	3.8 ±1.0***	77%***	-0.37
4. Taking insulin means other people see me as a sicker person.	3.1 ± 1.3	43%	2.4 ± 1.1**	21%**	0.56
5. Taking insulin makes life more difficult.	3.4 ± 1.3	58%	2.5 ± 1.2**	24%**	0.77
6. I'm afraid of injecting myself with a needle.	3.8 ± 1.4)	71%	1.9 ± 1.0**	11%**	1.47
7. Taking insulin increases the risk of low blood sugar levels (hypoglycaemia).	3.3 ± 1.1	44%	2.9 ± 1.1**	36%**	0.43
^8. Taking insulin helps to improve my health.	3.4 ± 1.2	50%	4.2 ± 0.8**	90%**	-0.79
9. Insulin causes weight gain.	2.9 ± 1.0	19%	2.8 ± 1.2	27%**	0.10
10. Managing insulin injections takes a lot of time and energy.	3.1 ± 1.3	42%	2.3 ± 0.9**	17%**	0.73
11. Taking insulin means I have to give up activities I enjoy.	2.9 ± 1.4	35%	2.4 ± 1.1***	25%***	0.34
12. Taking insulin means my health will get worse.	3.0 ± 1.4	39%	2.0 ± 0.8**	8.3%**	0.84
13. Injecting insulin is embarrassing.	2.5 ± 1.3	26%	1.9 ± 0.9**	9.0%**	0.54
14. Injecting insulin is painful.	3.5 ± 1.3	49%	2.2 ± 1.2**	19%**	1.03
15. It is difficult to inject the right amount of insulin at the right time.	3.2 ± 1.2	44%	2.6 ± 1.2**	28%**	0.55
16. Taking insulin makes it more difficult to fulfil my responsibilities.	2.9 ± 1.3	34%	2.3 ± 1.0**	19%**	0.49
^17. Taking insulin helps to maintain good control of my blood sugar.	3.8 ± 0.8	68%	4.1 ± 0.7***	92%**	-0.38
18. Being on insulin causes family and friends to be more concerned about me.	3.7 ± 1.1	66%	3.8 ± 1.0	75%***	-0.09
^19. Taking insulin helps to improve my energy levels.	3.4 ± 1.1	49%	3.9 ± 0.8**	81%**	-0.56

20. Taking insulin means I have to see the nurse/doctor more often.	3.5 ± 1.3	59%	3.3 ± 1.2	60%	0.10
Total ITAS score, mean ± SD		61.4 ± 12.4		48.6 ± 8.0**	1.24
Negative appraisal, mean ± SD		51.5 ± 11.2		40.7 ± 7.1**	1.17
Positive appraisal, mean ± SD		14.0 ± 3.0		16.1 ± 2.2**	-0.80

SD, standard deviation; A/SA, Agree/Strongly agree; ^ positive items; ** $p < 0.001$; *** $p < 0.05$

The study participants did not appear concerned about the commonly reported side effects of insulin therapy namely hypoglycaemia (44% vs. 36%, $d = 0.43$) and weight gain (19% vs. 27%, $d = 0.10$) regardless of insulin use.

4. Discussion

After adaptation, the ITAS used in this study presented a two-factor structure similar to the structure of the original ITAS [15] and the Chinese and Hong Kong translated versions [26, 27]. The internal consistency of the scale was also similar to the original questionnaire [15] and other translated versions [26, 27].

Consistent with previous studies, insulin-naïve participants in our study reported significantly stronger negative attitudes towards insulin therapy than insulin-users, while the latter reported stronger positive attitudes confirming the discriminatory validity of the tool [22, 27]. Similar findings were reported in Kenya [28] and Barbados [29].

In this study, the negative attitudes of non-insulin users to insulin therapy were mostly related to injection-related anxieties including fear of injection, pain from injection and the perceived burden associated with managing insulin injections. Fear of injection has previously been documented as a major factor for PIR among people with type 2 diabetes in South Africa [13, 14], and elsewhere [29]. Polonsky et al. [30] argued that this factor may be overstated and rather denotes the many negative beliefs about insulin or lack of knowledge about its use. Healthcare providers should offer patients information about tools to reduce injection-related worries [31]. In practice, healthcare providers could alleviate patients' injection anxiety by showing that insulin needles are small [32]. Insulin pens are relatively easy to use and may reduce anxiety, they should be introduced where possible.

People often perceive starting insulin as an indication of advanced diabetes, a 'last resort' [30]. In our study, most non-insulin using participants (63%) believed that taking insulin meant that their condition had worsened. These negative perceptions could be avoided by explaining to patients that the need for insulin, and subsequent titration, is part of the natural progression of diabetes. People with type 2 diabetes should be forewarned early in treatment that they will most likely require insulin in the future due to the nature of the condition rather than their own doing [30].

In contrast to most published literature [5, 33], participants in our study did not seem concerned about the side effects of insulin, such as hypoglycaemia and weight gain. Previous studies from South Africa have attributed this lack of concern to patients' lack of knowledge of insulin and diabetes [13]. Nonetheless, clinicians should discuss possible side effects with persons with type 2 diabetes.

In this study, participants who used insulin had less negative attitudes towards insulin therapy and seemed more knowledgeable about the benefits of insulin such as maintaining good blood sugar control or preventing complications. This reinforces that education and experience may reduce negative perceptions and beliefs towards insulin therapy [29]. Some insulin users in our study still had negative insulin appraisals, as reported by Holmes et al. [34]. The persistence or emergence of negative attitudes emphasises the need for evaluating PIR throughout the treatment continuum. The most common negative perception among insulin-using participants was that being on insulin causes family and friends to be more concerned. Participants were most likely relating their lived experience. Family and friends of insulin users may lack accurate knowledge and their concern could be due to myths and misconceptions that are prevalent in South African communities. Including the support structures of persons with type 2 diabetes, such as families and friends, in patient education may help address these misconceptions.

To the best of our knowledge, this study is the first study to measure PIR amongst South Africans using ITAS, a tool recognised and used globally. The use of an expert panel to ensure that the survey tool was relevant to the South African context and the inclusion of participants selected from various levels of care within the public healthcare sector are among the strengths of this study. Our study has some limitations. The use of interviewers to administer the questionnaire to illiterate participants instead of self-administration can be

viewed as a limitation. However, using trained interviewers who were conversant with the local languages is a necessity in South Africa because of the multilingual population and English is not the first language for many. Using trained interviewers is usually required to ensure that study participants fully understand the questionnaire. ITAS was also administered by interviewers in two studies conducted in Australia [35] and Barbados [29]. In the Australian study [35], the participants were interviewed by one of the researchers fluent in the local language, similar to what we did with our illiterate participants. Another limitation is that we cannot infer causality for the negative attitudes of non-insulin using participants.

5. Conclusions

This study found that insulin-naïve participants had more negative beliefs and attitudes towards insulin therapy than those who were taking insulin. The most commonly endorsed barriers to insulin therapy were the injection-related anxieties namely the perceived fear, pain and burden associated with injecting insulin. Psychological insulin resistance can be overcome by identifying and addressing patients' personal challenges and barriers to insulin therapy. South African clinicians should use the ITAS to assess positive and negative perceptions regarding insulin therapy in both insulin-naïve and insulin-treated people as well as evaluate interventions to reduce PIR.

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Conflict of interest

The authors have no conflict of interests to declare in relation to this work.

Authors' contribution

All authors are part of the Tshwane Insulin Project study group. PNP, PR, EMW conceptualized the study. PNP, JWM wrote the study proposal with input from PR, EMW. PNP, JWM trained the field workers and oversaw data collection. PNP managed the data.

PNP and JWM analysed and interpreted the data. PNP and JWM wrote the draft manuscript. PNP, PR, EMW provided critical review to the manuscript. All authors approved the final manuscript.

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