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ORIGINAL RESEARCH ARTICLE

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Development of the impact of weight on daily activities questionnaire: A patient-reported outcome measure

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Summary

While patient-reported outcome measures are available to evaluate health-related quality of life and functioning in obesity, existing measures do not evaluate the impact of excess weight and weight loss on the ability to perform regularly occurring daily activities. Three iterative sets of qualitative interviews were conducted in two countries (United States, n = 23; United Kingdom, n = 23) with individuals with body mass index ≥30 kg/m^2 to inform development of the Impact of Weight on Daily Activities Questionnaire (IWDAQ) for use in clinical trials to evaluate daily activity limitations associated with excess weight. Candidate concepts were selected based on the literature, expert opinion, and previously conducted qualitative research, after which the draft IWDAQ was developed and tested. Interviews included a brief concept elicitation phase, followed by cognitive debriefing during which the IWDAQ was refined based upon participants' feedback. The IWDAQ uses a novel, adaptive questionnaire design, such that clinical trial participants choose the three IWDAQ activities they would most like to improve with weight loss and rate the degree of limitation in each of these activities at baseline. By allowing individuals participating in trials to identify and monitor changes in the activities they most want to see improve with weight loss, the 19-item IWDAQ has the potential to detect the benefits of weight-loss treatment that individuals with obesity value most.

KEYWORDS

activity, activity limitations, obesity, patient-centred, qualitative

1 | INTRODUCTION

The worldwide prevalence of obesity has tripled since 1975, with an estimated 650 million adults, or 13% of the adult population, meeting the criterion for obesity (body mass index [BMI] ≥ 30 kg/m^2) in 2016.[1] Obesity is a risk factor for some of the leading causes of preventable death, including heart disease, stroke, and type 2 diabetes mellitus (T2D), as well as some types of cancers.[1] Despite the availability of dietary and behavioural interventions, pharmacologic agents, medical devices, and bariatric surgery, there remains an unmet need for treatments to facilitate weight loss and long-term weight management.

Decrements and improvements in functional status, health-related quality of life (HRQOL), and other aspects of patients' lives have been associated with obesity and weight loss, respectively.[2,3] Thus, the measurement of patient-reported outcomes (PROs) in clinical trials of weight-loss therapies is critical. Several obesity-specific measures of

HRQOL and functioning are available.[4-10] However, no instrument is available to assess the impact of excess weight and weight loss on the ability to perform regular day-to-day activities beyond basic activities of daily living (ADLs), such as the ability to get in or out of bed, feed oneself, or use a toilet, which may be impacted by severe obesity but might not be commonly impaired in clinical trial populations.

Thus, the objective of this study was to develop a PRO measure focused on daily activity limitations associated with excess weight, the Impact of Weight on Daily Activities Questionnaire (IWDAQ). The new measure is intended to complement functional assessments such as the Impact of Weight on Quality of Life-Lite (IWQOL-Lite)[5] and the Short Form-36 Health Survey (SF-36)[11] that are commonly used in clinical trials in obesity. Given the variability of impacts across the BMI spectrum and the variability of potentially important activities among individuals with obesity, a novel, flexible questionnaire design was employed for the IWDAQ, with the aim of evaluating the weight-related activity limitations that are most important to individuals with obesity.

What is already known about this subject

- Obesity is associated with decrements in functional status and health-related quality of life (HRQoL), and weight loss may result in improvements in functioning and HRQoL.
- The measurement of patient-reported outcomes (PROs) in clinical trials of weight-loss therapies is critical in evaluating treatment changes.
- No previously available PRO measures capture the impact of excess weight and weight loss on the ability to perform regular daily activities.

What this study adds

- The Impact of Weight on Daily Activities Questionnaire (IWDAQ) has been developed to evaluate daily activity limitations associated with excess weight.
- Three sets of qualitative interviews in two countries (United States, n = 23; United Kingdom, n = 23) with individuals with body mass index ≥30 kg/m^2 informed development of the measure.
- The 19-item IWDAQ uses a novel, adaptive questionnaire design: clinical trial participants choose the three IWDAQ activities they would most like to improve with weight loss and rate their limitation in each activity at baseline, thus capturing the benefits of weight-loss treatment that individuals with obesity value most.

2 | MATERIALS AND METHODS

Development of the IWDAQ followed a rigorous process consistent with industry standards as described in the US Food and Drug Administration (FDA) PRO guidance.[12] First, selection of relevant concepts and generation of the draft IWDAQ items were informed by a targeted review of the literature, analysis of existing qualitative data, and interviews with clinical experts. Semi-structured qualitative interviews (concept elicitation and cognitive debriefing) then were conducted with adults with obesity (BMI ≥30 kg/m^2) in the United States (US) and the United Kingdom (UK), during which the draft IWDAQ items were refined and the content validity of the measure was further supported. Finally, a translatability assessment was completed to ensure ease of translation for the IWDAQ and cultural equivalence in additional countries.

3 | CONCEPT SELECTION AND ITEM GENERATION

Initially, a targeted literature review was conducted to identify impacts of obesity on individuals' daily activities. The PubMed and Embase databases were searched for articles and conference abstracts assessing activity limitations among adults with obesity, through either qualitative research or the use of existing questionnaires/measures. From the relevant studies, the daily activities affected by excess weight were summarized and quantified.

In addition, a review of the results of concept elicitation interviews conducted with 38 adults with obesity (including both individuals with and individuals without T2D) during the development of the IWQOL-Lite Clinical Trials Version (IWQOL-Lite-CT),[4] as well as qualitative focus groups conducted with 61 adults with obesity or overweight collected during the development of the Weight-Related Signs and Symptom Measure (WRSSM),[13] further informed the selection of concepts for measurement in the new questionnaire. Specifically, these interview data were mined to identify daily or regularly completed activities that interview participants reported being limited by their current weight.

Based on the results of the literature review and previously conducted qualitative research, a preliminary draft of the IWDAQ was developed and included concepts that ranged from basic ADLs to potentially difficult social and physically demanding activities. The questionnaire was designed such that clinical trial participants would be able to choose three activities they would most like to improve with weight loss and to rate the degree of limitation in each of these activities at baseline. The same three activities could then be assessed for degree of limitation at subsequent visits throughout a clinical trial to allow for the tracking of activities relevant to each individual across the BMI continuum.

Individual interviews were then conducted with three US-based clinicians with expertise specific to obesity: one endocrinologist, one nurse practitioner, and one clinical psychologist with expertise in patient-centred research in obesity and weight management. At the beginning of these interviews, the clinical experts identified activities commonly reported as being impacted by excess weight, including activities that are relevant across all BMI obesity classes (ie, class 1: BMI = 30-34.99 kg/m^2; class 2: BMI = 35-39.99 kg/m^2 and class 3: BMI ≥40 kg/m^2) and

those relevant only to specific BMI groups (ie, lower vs higher BMI). The experts then reviewed and provided feedback on the draft IWDAQ, including the overall measurement approach and content. Each interview was conducted by telephone and lasted approximately 1 hour.

Based on the results of the interviews with clinical experts, minor revisions were made to the US version of the draft measure, which was then adapted for testing in the UK. The draft versions of the IWDAQ tested in the US and UK were extremely similar, with only a few minor wording differences. Both versions of the measure were then evaluated and refined through qualitative research conducted with individuals with obesity in each country.

4 | QUALITATIVE INTERVIEWS

4.1 | Interview participants

Qualitative research firms recruited 46 individuals to participate in the interviews, including 23 individuals in the US and 23 individuals in the UK. Trained medical recruiters screened potential participants for eligibility using a screening questionnaire. Eligible individuals were adults (aged ≥18 years), had a self-reported BMI of at least 30, had stable body weight (ie, experiencing a change of no more than 10 pounds within the previous 90 days), had tried to lose weight by dieting in the past, and were conversant in English. To ensure the sample was broadly representative of the BMI spectrum, participants in all three BMI classes were recruited (class 1: BMI = 30-34.99 kg/m^2; class 2: BMI = 35-39.99 kg/m^2; class 3: BMI ≥40 kg/m^2), with a target of 16 participants per class.

This study was reviewed and deemed exempt by RTI International's institutional review board prior to participant recruitment. All participants provided written informed consent before participating in the interviews.

4.2 | Interview procedures

Three iterative sets of 7 to 8 in-depth qualitative interviews were conducted in each country (for a total of 23 interviews per country). Each interview was conducted in person by two experienced qualitative researchers following a semi-structured interview guide. All interviews were audio-recorded and transcribed.

Each interview began with a brief concept elicitation exercise to explore how participants' weight impacted their lives. Specifically, this phase began with open-ended questions designed to identify the most salient day-to-day activities that were either influenced or limited by participants' weight.

Interview participants were then asked to complete and provide feedback on the draft IWDAQ and the overall approach to the questionnaire's implementation during the cognitive debriefing phase of each interview. Briefly, participants were asked to 'think aloud', describing their thought processes as they read the instructions, identified the three activities in which they would most like to see improve with weight loss, and rated the degree of their limitations on the IWDAQ. While in practice, IWDAQ respondents will rate their limitations in only the three activities they select as most important, interview participants were asked to rate their limitations in all of the activities to facilitate testing and refinement of the measure. Interviewers also posed follow-up questions designed to further elucidate the participant's comprehension and question-answering process, as well as to identify what participants deemed to be meaningful improvement at the item level. Finally, to gather further evidence regarding the content validity of the IWDAQ, all participants were asked whether the measure included any activities that were not relevant to their experiences or, alternatively, whether there were any important activities that did not appear to be adequately addressed by the existing items. Modifications to the draft questionnaire were based on the results of each set of interviews in both countries and evaluated in the subsequent set of interviews.

4.3 | Qualitative analyses

Following each round of interviews, research staff in each country debriefed and summarized key learnings from the interviews based on their field notes. Team members in the US and UK then met to discuss key concepts described by participants, as well as feedback pertaining to the draft measure to inform any modifications that might be warranted prior to the next set of interviews.

This step was then followed by more formal analysis facilitated by interview transcripts. Specifically, by using the transcripts and field notes, concepts of importance and potential problems with the new measure based on participant input were identified in each interview and compared with the results of other interviews to document the frequency with which these concepts and issues were reported. Participant quotes were also identified to illustrate rationale for key conclusions and decisions.

5 | TRANSLATABILITY ASSESSMENT

Between the second and third sets of qualitative interviews, a translatability assessment was conducted to assess the conceptual clarity and translatability of the draft IWDAQ across different languages. Linguists from eight different language groups (Russian, Zulu, Japanese, German, Hindi, French, Arabic, and Chinese) reviewed the instrument to identify any concepts, phrases, or components of the instrument that would be difficult to translate or appeared to be culturally specific.

6 | RESULTS

6.1 | Concept selection and item generation

6.1.1 | Literature review

A total of 12 publications describing the impact of weight on daily activities were identified for review.[14-24] The types and frequency of

activities limited by excessive weight varied across the studies, ranging from less complex (eg, walking, standing) to more complex (eg, doing household chores or yardwork, engaging in strenuous physical activity) activities. While ADLs, such as getting in and out of bed and using a toilet, were assessed through standard ADL measures in several studies, impairments were generally limited to individuals with more severe obesity than is common in the expected context of use for the IWDAQ (ie, weight loss clinical trials involving adults with BMI ≥30 kg/m^2). As anticipated, the literature review results indicated that adults with higher BMIs tended to experience greater limitations (and during simpler activities) than adults with lower BMIs. The review also confirmed that there was no existing measure of activity limitations that was 'fit for purpose' in clinical trial programs.

6.1.2 | Review of existing qualitative data

More than 20 potentially distinct categories of daily or routine activities were spontaneously reported by interview participants as being negatively impacted by their excess weight. In general, these activities fell into the following categories: physical activities (including recreational activities, exercise and playing with children); social or public activities (including going out to dinner, parties, or social events with friends, family or coworkers); intimate relationships (including romantic/sexual relationships with a spouse or dating); activities involving small seats or spaces (including getting into/fitting in seats in a variety of locations such as cars, airplanes, concert halls); and sleep (including issues falling and staying asleep, snoring/sleep apnea). Overall (and as expected), participants with lower BMIs tended to report fewer and less extreme impacts than participants with higher BMIs.

6.1.3 | Interviews with clinical experts

While each of the experts had recommendations for refinement of the initial draft measure, all three indicated that the concepts of measurement were consistent with the activities their patients most frequently reported as being limited by their weight. Furthermore, all three experts were supportive of the assessment strategy and noted that an instrument such as this would fill an unmet need to assess the impact of weight on daily activities.

6.2 | QUALITATIVE INTERVIEWS

6.2.1 | Participant characteristics

Table 1 summarizes the demographic and clinical characteristics of the interview participants (23 in each country) by BMI class. Consistent with the recruitment targets, the BMI classes were almost equally represented across the participant sample (BMI class 1: n = 16; BMI class 2: n = 15; BMI class 3: n = 15). The average age of the participants was 41 years (range, 21-66 years), and slightly over half (n = 27) were female. Four participants in the US had a diagnosis of T2D; none of the UK participants reported a T2D diagnosis.

6.2.2 | Concept elicitation

The activity limitations participants reported spontaneously prior to seeing the IWDAQ were generally aligned with the content of the IWDAQ and consistent with the results of the preceding research.

TABLE 1 Participant characteristics

	BMI Class 1[a] (n = 16)			BMI Class 2[a] (n = 15)			BMI Class 3[a] (n = 15)			
	US	UK	Total	US	UK	Total	US	UK	Total	Total (N = 46)
Age, mean (SD), y	40.8 (14.9)	38.9 (16.7)	39.8 (15.3)	35.7 (10.2)	40.5 (13.6)	38.3 (12.0)	39.6 (12.9)	47.7 (8.2)	43.4 (11.4)	40.5 (13.0)
	n	n	n (%)	n	n	n (%)	n	n	n (%)	n (%)
Sex										
Male	4	5	9 (56.2)	4	3	7 (46.7)	2	1	3 (20.0)	19 (41.3)
Female	4	3	7 (43.8)	3	5	8 (53.3)	6	6	12 (80.0)	27 (58.7)
Race										
White	5	8	13 (81.2)	4	8	12 (80.0)	3	7	10 (66.7)	35 (76.1)
African American	2	0	2 (12.5)	3	0	3 (20.0)	5	0	5 (33.3)	10 (21.7)
American Indian	1	0	1 (6.2)	0	0	0 (0.0)	0	0	0 (0.0)	1 (2.2)
Ethnicity										
Hispanic	1	0	1 (6.2)	0	0	0 (0.0)	0	0	0 (0.0)	1 (2.2)
T2D										
Yes	1	0	1 (6.2)	0	0	0 (0.0)	3	0	3 (20.0)	4 (8.7)
No	7	8	15 (93.8)	7	8	15 (100.0)	5	7	12 (80.0)	42 (91.3)

Abbreviations: BMI, body mass index; SD, SD; T2D, type 2 diabetes mellitus.

[a]Class 1 = BMI between 30.00 and 34.99; Class 2 = BMI between 35.00 and 39.99, inclusive; Class 3 = BMI 40 and higher.

TABLE 2 Summary of activity limitations associated with obesity reported prior to review of the IWDAQ (N = 46)

	BMI class 1[a] (n = 16)			BMI class 2[a] (n = 15)			BMI class 3[a] (n = 15)			
	US, n	UK, n	Total, n (%)	US, n	UK, n	Total, n (%)	US, n	UK, n	Total, n (%)	Total (N = 46), n (%)
Moderate exercise or recreational activities	4	3	7 (43.8)	3	3	6 (40.0)	3	3	6 (40.0)	23 (50.0)
Playing with or taking care of children	2	5	7 (43.8)	4	4	8 (53.3)	3	2	5 (33.3)	20 (43.5)
Physical activities at work	4	2	6 (37.5)	1	1	2 (13.3)	5	6	11 (73.3)	19 (41.3)
Strenuous exercise or recreational activities	4	5	9 (56.3)	2	2	4 (26.7)	3	1	4 (26.7)	17 (37.0))
Walking short distances	1	1	2 (12.5)	—	2	2 (13.3)	3	2	5 (33.3)	10 (21.7)
Buying clothes	—	—	—	—	3	3 (20.0)	—	6	6 (40.0)	9 (19.6)
Socializing with friends or family	1	1	2 (12.5)	—	2	2 (13.3)	1	2	3 (20.0)	7 (15.2)
Household tasks	—	1	1 (6.3)	—	2	2 (13.3)	1	1	2 (13.3)	5 (10.9)
Sexual activity	2	2	4 (25.0)	—	—	—	—	1	1 (6.7)	5 (10.9)
Leisure activities or hobbies	—	1	1 (6.3)	—	1	1 (6.7)	—	1	1 (6.7)	3 (6.5)
Shopping for groceries or other necessary household items	—	1	1 (6.3)	—	—	—	—	2	2 (13.3)	3 (6.5)
Getting to small places/fitting in seats	—	—	—	—	—	—	2	1	3 (20.0)	3 (6.5)
Dating or developing romantic relationships	—	—	—	2	—	2 (13.3)	—	—	—	2 (4.3)
Outdoor tasks	—	—	—	—	1	1 (6.7)	—	1	1 (6.7)	2 (4.3)
Going to events or parties	1	—	1 (6.3)	—	—	—	—	—	—	1 (2.2)
Toileting	—	1	1 (6.3)	—	—	—	—	—	—	1 (2.2)

Abbreviations: BMI, body mass index; IWDAQ, impact of weight on daily activities; UK, United Kingdom; US, United States.
[a]Class 1 = BMI between 30.00 and 34.99; Class 2 = BMI between 35.00 and 39.99, inclusive; Class 3 = BMI 40 and higher.

TABLE 3 Participants' verbatim quotations about activity limitations associated with obesity (N = 46)

Activity	Quotations
Strenuous exercise or recreational activities	I think…most of them are problems like walking, running, hiking…Activities like cleaning around the house, because you just get tired quicker. [BMI: 40.6] Like, if I go to my little Zumba classes, I have to limit what I do because I cannot do…the full thing and jumping jacks and all that stuff. [BMI: 57.9] When I'm running, I feel like I'm carrying too much weight that I cannot run very far or for very long and I feel a bit clumsy and heavy doing it, you know. [BMI: 32.3]
Moderate exercise or recreational activities	I do feel I have to sit down, I cannot stand for a long period of time, so in lectures…it's quite a practical one where we are all [standing] about [and] I feel I have to seek out a seat after a period of time. [BMI: 32.9]
Household tasks	Yeah, it's just doing things like mowing the yard…it's not quite as easy as it used to be. [BMI 39.1] Throughout the day [I'm] postponing chores like laundry or the dishes or anything like that. Anything that takes like a lot of physical movement, I'll push it off a little bit. [BMI 40.6]
Socializing with friends or family	It's kind of embarrassing so it's not a kind of physical limitation of going out and socializing apart from walking here and there, but you can sit down and socialize. It's the, um, insecurity of people thinking of you. [BMI: 33.4]
Buying clothes	I used to love to go shopping, just to browse, not buy anything, but I'm limited to those activities now because of my weight. [BMI: 44.4]
Playing with or taking care of children	I've got a son who is 9 years old and…I can kick a ball around with him, but I cannot exactly run around for it because I'm goosed after not a lot of time at all….[BMI: 45.5]
Sexual activity	…being overweight and sexual activity in general is just hard because you are, you are moving a lot more around. [BMI: 55.5] So I mean we have been together 10 years but like it [sexual activity] used to be a lot better but now I do just get really self-conscious of like, you know, taking my clothes off and things like that…it does really affect me. [BMI: 30.5] I was probably about just 15, 20 pounds lighter, a little more active than I've been over the last several years, so definitely can tell a little bit…Stamina maybe. I do not know. In the bedroom… [BMI: 32.5]

Abbreviation: BMI, body mass index.

Specifically, when asked about the ways in which their weight limited their daily lives, participants across the BMI spectrum most frequently noted limitations in moderate exercise, playing with or taking care of children, physical activities at work, strenuous exercise, and walking short distances. Limitations in other activities were less frequently mentioned overall and were generally more common among those with higher BMIs; these activities included socializing with friends or family, completing household tasks, sexual activity, leisure activities or hobbies, shopping for groceries or other household items, dating, performing outdoor tasks, and going to events or parties. In discussing each of these activities, participants indicated that their excess weight limited the ease, duration, or frequency with which they could engage in these activities and, in some cases, prevented them from engaging in the activity altogether. Table 2 shows the frequency with which each type of activity limitation was reported by participants across BMI classes and countries during the concept elicitation exercise, and Table 3 presents selected sample quotes describing participants' experiences with various activity limitations.

6.2.3 | Cognitive debriefing

The overall approach and all components of the IWDAQ, including introductory text describing the purpose of the measure, the instructions, questions, and response options, were evaluated in detail and refined across the three interview rounds of interviews. Modifications to the introductory text and instructions were minor, and no changes to the response options (ranging from 1, 'Not at all', to 5, 'An extreme amount') were required.

Among the 20 concepts included within the draft IWDAQ (see Table 4), the majority of participants easily identified the three types of activities they would most want to see improve with weight loss and indicated that this was an appropriate number of activities to assess over the course of the clinical trial. In addition, participants commonly noted that improvement in the three activities identified would constitute a meaningful change in their lives.

On the basis of participant feedback, two types of activities in the original list—'Leisure activities' and 'Travel'—were removed from the questionnaire, primarily due to redundancy and overlap with other concepts. The descriptions of eight items—'Getting up from a chair', 'Sleep', 'Moving around the house', 'Walking short distances', 'Playing with or taking care of children', 'Socializing with friends or family', 'Socializing with people you don't know' and 'Moderate exercise'—were refined across the iterative sets of interviews. Most commonly, the activity descriptions were modified to clarify the intent of the item by providing additional detail or altering examples. For example, 'Sleep' was modified to 'Getting a good night's sleep' and the

TABLE 4 Frequency of item endorsement (response ≥ a little) and frequency of inclusion among the top three activities (US and UK combined)

	BMI class 1[b] (n = 16)		BMI class 2[b] (n = 15)		BMI class 3[b] (n = 15)		Total sample (N = 46)	
Concept[a]	Endorsed[c]	Top 3	Endorsed[c]	Top 3	Endorsed[c]	Top 3	Endorsed, n (%)[c]	Top 3 (n)
1. Bathing or showering	3	2	2	1	4	1	9 (19.6)	4
2. Dressing or undressing	8	1	6	3	6	1	20 (43.4)	5
3. Getting up from a chair	4	-	3	–	8	–	15 (32.6)	–
4. Getting up from the floor or ground	7	1	10	3	13	6	30 (65.2)	10
5. Sleeping	7	4	2	–	8	2	17 (37.0)	6
6. Moving around the home	2	–	3	1	7	1	12 (26.1)	2
7. Walking short distances	3	–	1	–	9	1	13 (28.3)	1
8. Leisure activities or hobbies	3	–	2	1	2	1	7 (15.2)	2
9. Household tasks	4	–	5	3	8	4	17 (37.0)	7
10. Shopping	–	–	–	-	8	–	8 (17.4)	–
11. Getting to places[d]	1	–	–	–	–	–	1 (2.2)	–
12. Playing with or taking care of children	12	8	11	8	8	6	31 (67.4)	22
13. Socializing with friends or family	3	1	3	1	6	–	12 (26.1)	2
14. Socializing with people you do not know well	7	2	5	2	10	3	22 (47.8)	7
15. Dating or developing romantic relationships	1	–	3	2	2	–	6 (13.0)	2
16. Sexual activity	11	6	8	5	8	1	27 (58.7)	12
17. Outdoor tasks	9	3	4	2	8	3	21 (45.7)	8
18. Physical activities at work	9	5	11	5	14	4	34 (73.9)	14
19. Moderate exercise	12	7	12	1	15	6	39 (84.8)	14
20. Strenuous exercise	14	8	13	7	13	5	40 (87.0)	20

Abbreviations: BMI, body mass index; UK, United Kingdom; US, United States.

[a]Item stems have been truncated to facilitate presentation.

[b]Class 1 = BMI between 30.00 and 34.99; Class 2 = BMI between 35.00 and 39.99, inclusive; Class 3 = BMI 40 and higher.

[c]Endorsed = responded ≥ *a little* when responding to the item.

[d]Item 11 was removed after round 1.

examples of activities that might be considered moderate exercise were modified slightly in both countries based on participant feedback. The descriptions of the remaining concepts remained the same across interview rounds based on participants' feedback: 'Dressing or undressing', 'Getting up from the floor or ground', 'Household tasks', 'Shopping', 'Dating or developing romantic relationships', 'Sexual activity', 'Outdoor tasks', 'Physical activities at work' and 'Strenuous exercise'. Participants across rounds and countries consistently reported that the items retained across all three rounds of interviews were relevant to their experiences, clear, and easy to understand.

The content validity of the IWDAQ is further supported by the frequency with which participants indicated limitations in the set of activities addressed in this measure. As noted in the Methods section, interview participants were asked to rate the extent of their limitations in all activities, rather than only the three selected as the most important, as will be done in practice. Table 4 shows the frequency with which each activity was at least 'A little' limited by their weight and the frequency in which a specific item/activity was included among the three activities participants most wanted to see improve with weight loss ('Top 3').

The most frequently endorsed activity across all three rounds was 'Strenuous exercise,' which was also one of the most highly endorsed top 3 most important activities in which to see improvement with weight loss reported by participants. The most highly endorsed top 3 activities included 'Playing with or taking care of children', followed by 'Strenuous exercise', 'Physical activities at work', 'Moderate exercise' and 'Sexual activity', which were also among the most highly endorsed activities in general.

6.3 | Translatability assessment

The results of the assessment were positive. The majority of recommendations pertained only to potential wording in the target language to ensure cultural equivalence and did not indicate that changes were needed to the source English versions of the IWDAQ. Only a few minor changes were made in both the US and UK versions of the questionnaire prior to the third round of interviews.

7 | DISCUSSION

Because the objective measurement of weight loss fails to capture improvements in patients' functioning and health-related quality of life, PRO measures such as the IWQOL-Lite and SF-36 are commonly included in obesity clinical trials to facilitate a more comprehensive assessment of treatment benefit. These and newly emerging measures, such as the IWQOL-Lite-CT and WRSSM, assess general health status or important physical and psychosocial impacts of obesity and have the potential to improve with weight loss. However, because the impacts of obesity vary tremendously not only by BMI but also by demographic characteristics such as age, sex, and marital status, these measures may not capture certain impacts of obesity that are most troublesome to subgroups of patients. Importantly, a 'one-size-fits-all' approach does not allow the capture of improvements in patients' daily lives attributable to weight loss, such as a new found willingness to date or stamina when playing with children, that may be very important to certain groups of individuals but are too circumscribed to be addressed in a static PRO measure. By allowing patients to identify and then track changes in the daily life activities they most want to see improve with weight loss, the IWDAQ represents a unique and complementary approach to the assessment of treatment benefit in clinical trials. Furthermore, this new dynamic measure has the potential to detect treatment benefits related to daily life activities that are most important to individuals with obesity, which may make it particularly valuable in the context of clinical practice.

While a dynamic approach is relatively novel in the context of assessing improvements in clinical trials, the process used to develop the IWDAQ is not. Specifically, the development of the IWDAQ is consistent with the review criteria outlined in the 2009 FDA PRO guidance. Item generation was based upon extensive input from individuals with obesity in addition to the results of a targeted literature review and consultation with clinical experts. Additional qualitative research was then conducted in both the US and UK to refine and further support the content validity of the measure. Interview participants varied in their demographic characteristics and covered the three BMI classes typically targeted for participation in clinical trials.

While the measurement properties of the IWDAQ have yet to be demonstrated, it is anticipated that the measure will have no or minimal floor and ceiling effects given the range of activities offered for selection and given the finding that all 46 of the qualitative research participants indicated weight-related limitations spanning multiple activities. Importantly, all interview participants indicated that the three types of activities they would most want to see improve with weight loss were included in the IWDAQ and that these three activities were easy to identify and rate using this measure. In addition, interview participants consistently reported that improvement in any of the three identified activities would be meaningful and that tracking changes in specific activity limitations made sense to them. The totality of these data support use of the IWDAQ to monitor changes in activity limitations important to individuals with obesity. A psychometric evaluation is planned using data from an upcoming clinical trial to evaluate item performance, test-retest reliability, construct validity, responsiveness and thresholds for meaningful change.

The strengths and limitations of this study are noted. A strength of the study is that interviews were conducted in two countries in different regions of the world, although it is acknowledged that the cultures across the two countries are somewhat similar. While there are minor wording differences between the US and UK versions of the IWDAQ, the concepts themselves were equally applicable to interview participants in both countries. Furthermore, the results of the translatability assessment did not identify any items that would be difficult to translate or adapt across the eight selected language groups.

Despite the results of the translatability assessment, it may be challenging to ensure that each of the activities are both culturally appropriate and conceptually equivalent across a wide range of disparate countries. Therefore, prior to its use in multinational clinical trials,

a rigorous cultural adaptation, including cognitive debriefing interviews with patients in each country and language of administration as a part of the translation process[25] is recommended to ensure the content validity of the IWDAQ in each context of use. In addition, migration of the measure to an electronic platform is planned.

8 | CONCLUSIONS

Given the rigour with which it was developed and the high degree of endorsement from both individuals with obesity and clinicians, it is anticipated that the IWDAQ will provide highly valuable data when administered in the context of clinical trials. Specifically, this instrument has the potential not only to support approval and reimbursement decisions, which are primarily based on changes in weight, but also to demonstrate the degree to which weight loss translates into improvements in the daily activities that matter most to individuals with obesity.

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CONFLICT OF INTEREST

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