



Development of an Assessment Tool for Completion by Patients with Overweight or Obesity

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ABSTRACT

Introduction: Discussions of weight-management strategies between patients and healthcare providers can yield positive outcomes for people with overweight or obesity. Nonetheless, people with overweight or obesity encounter communication challenges and other barriers to

pursuing effective weight-management strategies with their healthcare providers. The aim of this study was to develop a new self-completed assessment tool to initiate and facilitate conversations related to weight management between patients and healthcare providers.

Methods: Developing the assessment tool involved a series of steps and draft versions of the tool, based on feedback from key opinion leaders in the field of obesity ($N = 4$) and input from people with overweight or obesity ($N = 18$). Three iterative rounds of qualitative interviews were conducted in the USA. A targeted review of prior qualitative research was conducted to identify common and important impacts of obesity on patients' functioning.

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Standard qualitative analytical methods were used to identify concepts of importance in a concept elicitation exercise during the interviews and were evaluated for potential inclusion in the tool. Potential problems with the tool were flagged during cognitive debriefing of the draft tool.

Results: During 18 individual interviews, participants referenced the impact of their weight on their lives, including health and comorbidities, physical function, emotional/mental functioning, social life, and physical appearance. Over the course of the tool's development, 24 common and important impacts of obesity on patients' functioning were reduced to a final set of eight concepts in the final tool that were deemed important and relevant to both patients and key opinion leaders.

Conclusions: The assessment tool is a five-item, self-completed measure expected to foster patient self-advocacy for individuals with overweight or obesity by giving them an opportunity to define their weight-management goals and discuss these, along with various medical interventions, with a healthcare provider.

Keywords: Obesity; Overweight; Patient-reported; Communications

Key Summary Points

Why carry out this study?

People with overweight or obesity may face communication challenges and other barriers to pursuing effective weight-management strategies with their healthcare providers.

The aim of this study was to develop a patient-completed assessment tool to facilitate conversations related to weight management between patients and healthcare providers.

What was learned from the study?

A five-item, patient-completed measure was rigorously developed to encourage and facilitate conversations regarding weight between patients and healthcare providers.

The tool is expected to foster patient self-advocacy for individuals with overweight or obesity by giving them an opportunity to define their weight-management goals and discuss these, along with various medical interventions, with a healthcare provider.

The tool provides insight into patients' past challenges and goals for weight management, thus paving the way for patient-centered discussions of weight-management strategies with providers.

INTRODUCTION

Obesity, an adiposity-based chronic disease, and its complications are contributing to a global health crisis [1–3], with 13% of the world's population having obesity in 2016 [4]. In the USA, the prevalence of obesity increased from 30.5% in 1999–2000 to 42.4% in 2017–2018 [5]. Obesity-related comorbidities are numerous, including cardiometabolic disease (metabolic syndrome and increased cardiovascular risk), dysglycemic-based chronic disease including type 2 diabetes, and reproductive disease [6–10]. In addition to these health risks, health-related quality of life (HRQOL) impairments associated with obesity are significant and increase with greater severity of obesity [11]. Weight loss is generally associated with improvements in HRQOL and reductions in obesity-related comorbidities [12, 13].

Increasingly, obesity is understood as a multifactorial and chronic disease with environmental, sociodemographic, behavioral, psychological, physiologic, and medical determinants [14, 15]. The ACTION (Awareness, Care, and Treatment In Obesity maNagement) study to examine obesity-related perceptions, attitudes, and behaviors among 3008 adults with obesity and 606 healthcare providers (HCPs) in the USA found that people with obesity who had maintained a weight loss of at least 10% for a year were more likely to report having received a medical diagnosis of obesity and to have discussed a weight-loss plan with an HCP [16].

Despite the positive association between patient–HCP communication and weight loss, people with overweight or obesity encounter barriers to pursuing effective weight-management strategies with their HCPs [17]. Such barriers include persistent stigma, suboptimal treatment, and communication challenges, particularly in the primary care setting [18]. A joint consensus statement with recommendations to eliminate weight bias was developed by a group of multidisciplinary international experts [19]. Even among HCPs who report being comfortable with weight-related conversations, time constraints limit these efforts. In the ACTION study, only 24% of people with obesity had a scheduled follow-up after an initial weight-related conversation with an HCP [17]. In the primary care setting, open and positive patient–provider communication and increased awareness of patients’ and providers’ respective beliefs can improve weight-management discussions and interventions [18, 20].

The purpose of this study was to develop a brief, self-completed assessment tool to facilitate communications between patients with overweight or obesity and their HCPs about the impact of excess weight on patients’ lives (as perceived by the patient), paving the way for an open dialog about treatment options. To maximize the utility of the tool, an iterative and systematic development process was followed with concept identification and tool modifications guided by input from clinical experts and individuals with overweight or obesity.

METHODS

Study Design Overview

The patient assessment tool was developed iteratively (Fig. 1), beginning with the identification of common and important impacts of obesity on patients’ functioning identified during prior qualitative research conducted with patients during development of the validated Impact of Weight on Quality of Life–Lite Clinical Trials questionnaire (IWQOL-Lite-CT) [21–23] and the Impact of Weight on Daily Activities Questionnaire (IWDAQ), two obesity-specific patient-reported outcome (PRO) measures [24]. An initial version of the tool, addressing key concepts, was developed and subsequently refined on the basis of feedback from key opinion leaders (KOLs) in the field of obesity. Three iterative rounds of qualitative interviews were then conducted with individuals with overweight or obesity to further refine and maximize the content validity of the tool. Considering the results of all patient interviews, the same KOLs reviewed the revised tool and provided input for its finalization.

Study Participants

Adult men and women in the USA meeting the following inclusion criteria were eligible to participate in web-enabled patient interviews: an age of at least 18 years; body mass index (BMI; kg/m²), based on self-reported weight and height, greater than 30 or 27.0–29.9 with at least one weight-related comorbidity (e.g., musculoskeletal pain, cardiovascular disease, sleep apnea, prediabetes, or type 2 diabetes); previous weight-loss attempts; interest in losing weight and discussing weight with an HCP; ability and willingness to participate in a 1-h interview in English; and access to a computer or tablet with a video camera and high-speed internet (to participate in the interview). Women who were pregnant at the time of the study, those self-reporting Cushing syndrome or hypothyroidism, and those self-reporting a diagnosis of bipolar disorder or schizophrenia were excluded.

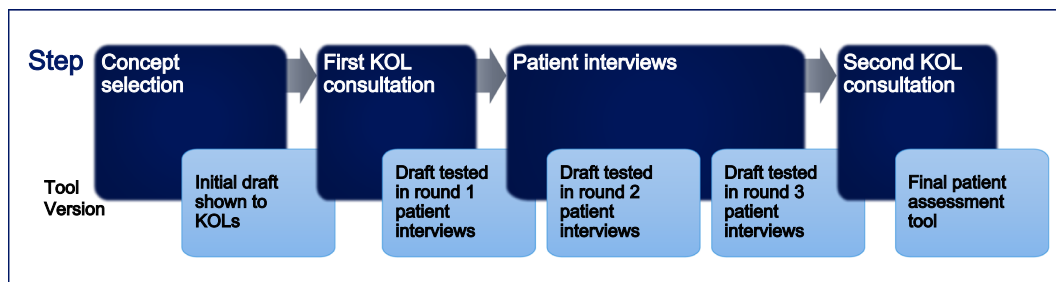


Fig. 1 Study overview. *KOL* key opinion leader

Tool Development

Step 1: Development of an Initial Draft

To identify the most common and important impacts of obesity from the patient perspective for inclusion in the initial draft of the tool, the study team collaboratively reviewed the results of previous qualitative patient interviews conducted during development of two obesity-specific PRO measures, the validated IWQOL-Lite-CT [21–23] and the IWDAQ [24], as well as rates of endorsement for individual IWQOL-Lite-CT items within several phase 3a clinical trials of semaglutide for weight management. To optimize the potential relevance and importance of selected concepts, those endorsed by at least 35% of patients were considered. After discussion among the study team, additional concepts were identified for tool inclusion to further facilitate communication and engage patients in information sharing (e.g., by reflecting previous weight-loss attempts and interest in speaking with an HCP about treatment options).

Three clinicians (R.L.K. and K.N., plus a nonauthor clinician) and one patient advocacy representative (J.N.) provided insight on patient–HCP communications regarding weight and provided feedback on drafts of the patient assessment tool before and after testing it with patients.

Step 2: Patient Interviews and Tool Refinement

L&E Research, a qualitative research firm, recruited participants with overweight or obesity for qualitative patient interviews using their proprietary nationwide panel. A diverse sample with regard to sex, educational levels, ages, and

US geographic areas, as well as general representation, was targeted. The study materials and protocol were reviewed on ethical grounds by the institutional review board of RTI International, and the study was deemed exempt from full review. The study was conducted in accordance with the 1964 Declaration of Helsinki and its later amendments. All participants provided verbal informed consent to participate in the study and have their responses and characteristics published in summary form, which was considered sufficient for a non-interventional interview study, prior to initiation of the interviews. Each 60-min, web-conference interview was audio recorded and conducted by two experienced qualitative interviewers (T.M.B. and C.K.). Each interview began with a brief introduction to the study followed by a concept elicitation exercise, wherein interview participants answered open-ended questions about the impacts of obesity on their lives that were most important to them. Following the concept elicitation portion of each interview, cognitive debriefing was conducted to assess how participants interpreted the items included in the tool and selected their responses, to identify any refinements necessary to facilitate use of the tool, and to gather additional information about participants' perceptions of the concepts included in the tool and any important concepts that may have been missing.

Analyses

Immediately following each interview, key learnings were identified and discussed by the interviewers. This step was followed by more formal thematic analysis facilitated by interview

Table 1 Characteristics of participants by round

Characteristic	Round 1 (<i>n</i> = 6)	Round 2 (<i>n</i> = 6)	Round 3 (<i>n</i> = 6)	Total (<i>n</i> = 18)
Age (years); mean (SD), range	38.5 (14.9), 21–56	45.0 (18.5), 19–66	39.0 (14.8), 26–63	40.7 (15.5), 19–66
BMI (kg/m ²), <i>n</i> (%)				
27–29.9	0 (0.0)	1 (16.7)	1 (16.7)	2 (11.1)
30.0–34.9	2 (33.3)	2 (33.3)	1 (16.7)	5 (27.8)
35.0–39.9	2 (33.3)	2 (33.3)	2 (33.3)	6 (33.3)
40+	2 (33.3)	1 (16.7)	2 (33.3)	5 (27.8)
Sex, <i>n</i> (%)				
Male	3 (50.0)	3 (50.0)	3 (50.0)	9 (50.0)
Female	3 (50.0)	3 (50.0)	3 (50.0)	9 (50.0)
Race, <i>n</i> (%)				
Asian	0 (0.0)	1 (16.7)	0 (0.0)	1 (5.6)
Black	2 (33.3)	2 (33.3)	2 (33.3)	6 (33.3)
Hispanic	2 (33.3)	0 (0.0)	1 (16.7)	3 (16.7)
Native American	0 (0.0)	0 (0.0)	1 (16.7)	1 (5.6)
White	2 (33.3)	3 (50.0)	2 (33.3)	7 (38.9)
Education, <i>n</i> (%)				
High school	1 (16.7)	1 (16.7)	1 (16.7)	3 (16.7)
Some college	3 (50.0)	1 (16.7)	2 (33.3)	6 (33.3)
College	2 (33.3)	2 (33.3)	2 (33.3)	6 (33.3)
Graduate degree	0 (0.0)	2 (33.3)	1 (16.7)	3 (16.7)

Participant characteristics were self-reported
BMI body mass index, *SD* standard deviation

transcripts and field notes. Specifically, the relative importance and frequency with which concepts were reported was tabulated. On the basis of participants' feedback, the clarity and ease of response to each item, as well as the overall comprehensiveness of the tool, were evaluated. If new concepts were mentioned and deemed relevant, they were added to the tool; item modifications were also driven by participant input.

RESULTS

Step 1: Development of an Initial Draft

On the basis of previous qualitative research, 24 specific concepts related to the impact of obesity on patients' lives were identified and informed development of the initial draft of the tool. These concepts were transformed to positively worded statements by the inclusion of a common stem ("If I lost weight, I would..."), and agreement with each statement was measured on a five-point verbal response scale ranging from strongly agree to strongly disagree

Table 2 Concept elicitation patient feedback ($N = 18$)

Experiences with weight loss and the impact of obesity

Challenges with keeping weight off

I live near quite a bit of fast food restaurants. Eating fast food has always been the norm for me

I just have a hard time resisting [overeating]. If I just get the idea in my head of eating something I can't let go of it

I was working and going to school all the time when I was really worried about it [weight]. It was really hard for me to actually sit there and be like "I'm going to eat this, this, and this." It was just easier for me to go grab something really quick and then go to school and then go to work right afterwards

Some of the healthier foods are quite a bit more expensive, or they require a little bit more prep time

We have rainy winters, unfortunately, so that kind of prevents walking

You start craving the things that you miss, and then you don't see as much success, or you're not losing it as fast as you would like, then you start to forget and go back to your old ways

I get tired of eating the same thing. So, it was easier for me to go to frozen foods and grab a sandwich on the way home or eating like I said, pizza twice a week... and it was more or less economical as well

My biggest struggle with trying to lose weight is just never having the amount of time for meal prep ahead of time so I can control what I'm eating and the ingredients

Effect of the COVID-19 pandemic

One of the things that was working really well for me pre-COVID was for, I guess, almost 3 years is I'd walk a lot at work... But bam, COVID hit and it just threw my son and I, everything, my whole world, just having to cope with all of that, everything that comes with that

I've kind of used this pandemic that we're in to... get my body right and try to start eating better and exercising more. So, I actually started bicycling and jogging around my community

I haven't weighed myself in a while, but I know I've probably gained a little bit of weight from COVID

I would say the activity pre-COVID was a lot more significant than right now where I'm just tied into the computer, sitting in the chair and the bathroom is only maybe no more than five steps away

Impact of weight on participants' lives

I have a little girl... And she was running around the house and... I ran up the steps after her and I was out of breath. And I got to the top of my stairs, I'm like... I got to make a change here. I said, there's no way I should be out of breath going about maybe 15 steps up... So that was an eye-opener moment for me

I feel like my mobility is slowly getting more limited and that's kind of annoying and depressing. I'm taking a lot of medications and I wish I wasn't

I feel like my weight affects my life because it's always awkward being the biggest person in the room. I feel like in terms of the medical system, it feels like no matter what I could possibly come to the medical system for, the first thing is always going to be blamed on my weight

I'm at work kind of thing and it's really easy to just be worried about what my coworkers are thinking... Then just even like say having fun, going to an amusement park. I'm always worried to get on a certain ride or something that I really used to enjoy

I'm always just feeling kind of fatigued and sluggish. I need coffee to get going

Table 2 continued

I travel a lot... it is more expensive for another seat, or being comfortable with the person next to you, and then just overall, being able to go to a restaurant and not getting the looks

I mean it definitely affects the clothes I can buy because skinny people get all the cool clothes... I think it affects work too just because I have a quasi-physical job where when I have to trudge a whole bunch of heavy stuff around... So I feel like if I was in better shape I probably wouldn't be so... drained after

Discussions with HCPs about weight loss

Positive interactions with HCPs

[His doctor said] 'I know you might be trying this, but I need you to try something else and let's just try a different way.' So, he referred me to a nutritionist... So it's kind of like, he wanted me to try to take a different approach and it's just... it was all for my health. And I was definitely appreciative of that

I mean, just a doctor bringing it up and not a random person in life makes it more comfortable automatically, because you know they're doing it for that purpose. They're not judging you. It's about helping you. So just a doctor bringing it up already makes it less abrasive sounding

So, I've had a doctor kind of like talk to me about some food choices. Not like, hey, you're going to need to... It was very like client-led or patient-led... it was very welcoming, and like, hey, let's just have a conversation. If you've mentioned being overweight, kind of where your thoughts are

Yeah, definitely, because it's like if they talk about it, it's like they care, hopefully. And they want to talk about it

Difficult interactions with HCPs

I guess it's been 15 years, 20 years, something like that. I've had the same doctor. He weighs considerably way more than me. So, I'm thinking that may be a reason why he doesn't approach me about my weight... I broached this subject as well during my exams with him. But nothing really ever happened. I guess, I subconsciously thought, it's up to me

[My doctor] didn't really offer any solutions, just like get some therapy or something like that. And so, I ended up just not going to him anymore and I changed doctors. But the feedback is always the same thing, it's like I want to help you, but first you have to lose weight so I can help you lose weight

Actually, it wasn't very comfortable. My doctor is young, I'm old, it's the first time that I saw her because my other doctor left the practice... She's just this little slip of a thing so it was just one of those aggravating things since I've never been a little slip of a thing and never will be a little slip of a thing... I have seen her since, but it was not a comfortable conversation. I think it's hard for someone who knows that they're overweight

It's very generic information that they give you... I felt really annoyed about it actually. Because especially one of the doctors in the past who said that was fatter than I was

Willingness to use prescription medication to aid weight loss

Willing to use medications to aid weight loss

I was willing to take prescription medication to help me lower my weight. I was at that point

If that's what I had to do [take prescription medication], I would have

I definitely would try something, for sure. Let's just say that. I definitely would. I'm very concerned about the side effects... So that's the concerning part... if I went to a doctor tomorrow and they said, 'Try this new weight loss prescription,' I would definitely try it. Let's just say that

Table 2 continued

Yeah, depending on what it is. Yeah. I didn't like the side effects from phentermine. But I mean, that was years ago. So, if it's more updated medication, I'd try it

Well, if it doesn't cost me a hundred-some dollars or more, but the side effect would probably be it

Adverse to taking medications to aid weight loss

Personally, I do not like medication. I like supplements because I do believe that they are different. But I do not like medication overall

I did not ever try weight-loss medications of any kind. I'm kind of anti-medication and I guess that's kind of what made the difference for me

It's too dangerous. My friend tried that one that... I can't remember. It doesn't allow you to absorb fat. And she'd keep messing her pants or having to run to the bathroom or... and I'm just going, that's definitely not for me

I'm not really a pill person, never been a pill person like even when I get headaches, I don't want to take medicine

HCP healthcare provider

(weight-loss benefit statements). The initial draft of the tool was updated on the basis of the KOLs' recommendations, which resulted in a version with 19 weight-loss benefit statements (reduced from the initial set of 24) for testing in the first round of patient interviews. KOLs stressed the importance of the tool's wording to avoid offending patients or suggesting blame or shame so that patients would feel comfortable discussing weight with their HCP. KOLs recommended using a friendly title (Feeling Frustrated About Your Weight) and introducing the tool in the context of obesity as a disease.

Step 2: Patient Interviews and Tool Refinement

A total of 18 adults participated in three rounds of interviews (six participants per round). The tool was refined following each round of interviews to incorporate feedback from concept elicitation and cognitive debriefing discussions. The overall sample had a mean age of 41 years and an equal representation of male and female participants; 38.9% of the sample was White with a mix of BMI categories, education levels, and geographic location within the USA (Table 1).

Concept Elicitation

Interview participants were asked to share their weight history, including the impact of weight on their lives and strategies they had employed to lose weight in the past, if any (Table 2). Most participants shared long-term struggles with their weight and reported multiple attempts to lose weight in the past, most commonly centering on diet changes ($n = 16$) and/or increased physical activity/exercise ($n = 14$). Despite some success with weight loss in the past, participants shared that the main challenge was weight maintenance (keeping the weight off). All participants referenced the impact of their weight on some aspect of their lives, including health/comorbidities ($n = 5$), physical function ($n = 4$), emotional/mental functioning ($n = 7$), social life ($n = 4$), physical appearance ($n = 6$), work/career ($n = 3$), and family life ($n = 2$). For all participants, in addition to losing a specific amount of weight, overcoming these weight-related negative impacts was an important goal.

All participants reported having discussions with physicians regarding their weight and weight loss in the past (Table 2). Most participants reported that the discussions had been initiated by their physicians ($n = 12$), while others reported either a combination of

Table 3 Weight-loss benefits patient feedback (item 1)**If I lost weight, I would.**

Agree/strongly agree	Neutral/disagree/strongly disagree
<i>a) Live longer</i>	
<i>(n = 16)</i>	<i>(n = 2)</i>
My son makes fun of how... what I eat, because I try my very hardest to eat healthy. And he's like, 'Dad, are you eating healthy because you want to live longer? You want to be around longer?' And, obviously, I told him, 'yes.'	Probably neutral. I understand that we can cause certain conditions, but I don't think it would have a spin of how long we are going to live because you can be a little overweight but healthy at the same time
Most statistics show that if somebody is in a healthier condition, they do live longer because they don't have other health conditions or it's not just living longer, but also living a better quality of life	Which is neutral... Because you can die from anything at any age
If I were to lose weight, I would have a healthier lifestyle, which would help make my heart stronger, I wouldn't be in as much pain, and I would be more active, which would allow me to live longer	
<i>b) Be healthier</i>	
<i>(n = 17)</i>	<i>(n = 1)</i>
'Be healthier,' absolutely. Strongly agree... it wasn't so long ago when I was pretty darn healthy and very active. And I approached life with zest. I approached it with zeal, I approached it with vigor. I was like hungry for experiencing everything that I desire to experience	I'd probably put neutral for that, too... you can still be healthy and a little overweight at the same time
I would like to have a long life, but more importantly, I want to be healthy in that long life	
If I lost weight, I would be healthier. I would agree with that as well	
<i>c) Improve other health conditions</i>	
<i>(n = 17)</i>	<i>(n = 1)</i>
Yeah, because the fewer pounds, the less exertion you have to make	I don't really have any other health conditions, so I put neutral
I know a lot of overweight people that developed high blood pressure, diabetes because of their weight... congestive heart failure due to their weight, so I strongly agree that it'll improve your health conditions if you had a healthy weight	
That's just from my own experiences, my cholesterol was getting kind of high, and I made some dietary lifestyle changes and my cholesterol dropped really quickly and my doctor was super happy	

Table 3 continued

If I lost weight, I would.**Agree/strongly agree****Neutral/disagree/strongly disagree***d) Have fewer aches and pains**(n = 18)**(n = 0)*

Definitely. I hurt my knee when I was in cheerleading and ever since I've been putting more weight, I can feel it more, then my feet hurt a lot more too

I know that from experience with just losing about a third of the weight that I needed to lose

Having this weight on my bones, I do have to sometimes take breaks just to be able to kind of rest my bones, or being in pain, having to take medicine to help soothe the pain

*e) Be out of breath less often**(n = 15)**(n = 3)*

I do think the extra weight definitely plays a part into being out of shape as well... I'm out of shape and I'm overweight. And that definitely makes it harder on myself when it comes to breathing

Right now, I'm struggling to run 1 mile, so I agree

Yes. I used to play tennis, but I stopped because I would get shortness of breath. So, I would strongly agree on that

I would put neutral because I'm not sure what it's caused by because I do smoke. I vape... I don't believe that my breathing is affected by my weight, personally

I would say it's a neutral because I wouldn't necessarily say that has something to do with weight. It could be the fact that I don't exercise enough

*f) Require fewer medicines**(n = 12)**(n = 6)*

I only know about it because I have some related health condition that if I wasn't in the weight situation I'm in, I probably wouldn't even have to take those medications

I strongly agree with that as well. The healthier you are... and the more appropriate your body's working, the more it's functioning as it should. It makes sense that you'd need less medicine for whatever ails somebody

Require fewer medicines. This is an agree for me, and that's only because I don't currently take a lot of medicine

I would put strongly disagree because I do not use any medication. I only use supplements and those supplements are due to me having a lack of certain metals that are needed for my body

I would probably say, personally, neutral because I don't take any medicines. I always take supplements, so I can't really relate to that

I would require fewer medications, I guess neutral. I think that's just because from my experience, I don't think any medication I'm on has definitely been, I think, a reflection of my weight

Table 3 continued**If I lost weight, I would.**

Agree/strongly agree	Neutral/disagree/strongly disagree
<p><i>g) Be able to bend or move around more easily</i></p> <p>(<i>n</i> = 15)</p> <p>I would agree with that... because I feel like even though I'm kind of big, I feel like I'm pretty agile. I take care of this house and I do all the work in the yard and all that stuff, so I'm not totally bad off, but I could improve</p> <p>I strongly agree. If your stomach doesn't get in the way you can get to your toes</p> <p>Yes, because I don't bend that well... at work and stuff, there's always these events where these little circular tables are jammed together, and my fat butt can't fit in between those spaces most of the time, so if I lost weight, at least I could maneuver around a lot easier</p>	<p>(<i>n</i> = 3)</p> <p>I would put strongly disagree. I still have my split from cheerleading, so I'm good for that one</p> <p>I would say that one's also a neutral... if I bend down and touch my feet, I have my stomach in the way sometimes, but I wouldn't necessarily say that if I was 25 pounds lighter if I'm still able to do that, because I think that's more of practice versus the actual weight itself</p> <p>Be able to bend over and move around more easily, I never had a problem, neutral</p>
<p><i>h) Be able to walk faster or farther</i></p> <p>(<i>n</i> = 14)</p> <p>'Be able to walk faster or farther.' Absolutely. I mean, that's like a no-brainer. Definitely agree. And I would love to do that</p> <p>I put agree... losing weight would definitely help with stamina and be able to go farther</p> <p>I would strongly agree for that, and just because I have to take more breaks, being heavier... but if I were to lose weight, I feel like I would have less chance of having to take those</p>	<p>(<i>n</i> = 4)</p> <p>I would say I'm neutral for that. I pretty much already go everywhere... But maybe if I lost a bit of weight, it could go even more</p> <p>I disagree with that... I can't say that that is a true statement, because I do walk over 2 miles round trip</p> <p>I'll say neutral. I walk slow in general... Because my walking is not like I'm in a rush to be anywhere</p>
<p><i>i) Be more physically active</i></p> <p>(<i>n</i> = 15)</p> <p>Of course, strongly agree. From the previous questions, I'd be more active if I would lose so much weight</p> <p>I think you would just have more energy to do the things you want to do. Sometimes when you're overweight, a tendency to get sluggish, or you might grab a bag of potato chips versus going out for a walk</p> <p>Yes, I think it just comes with the same notion of just weighing less, being able to move much more easily, so being more physically active as well, I say strongly agree</p>	<p>(<i>n</i> = 3)</p> <p>I would say disagree. Again, based on my own physical conditions, I wouldn't say that I would be less physically active under my current weight condition</p> <p>I disagree with that because I was pretty physically active</p>

Table 3 continued

If I lost weight, I would.**Agree/strongly agree****Neutral/disagree/strongly disagree***j) Have more energy or stamina**(n = 16)*

I'd love to have more energy and stamina to do not only the things I want to do, but the things that my son wants for us to do

If I still have any kind of remnants of my sleep apnea, just losing the weight would probably ease that, and I'd probably have more restful sleep, which means I'd have more energy, and not having to carry such a heavy load everywhere would probably help me out on the stamina front, so that'd be good

(n = 2)

I would say a neutral on that because if I lose weight, I can't say that I would have more energy or stamina. It's possible. I, in general, have a lot of energy, so I don't know if me losing more weight that will increase my energy or stamina. Have more energy or stamina, actually I have less of it today, but... that's an old age thing. I would have to say neutral

*k) Be able to keep up with family and friends**(n = 11)*

I can push myself to keep up with my family when we go on hikes and stuff, it would definitely be much easier to do harder hikes and more longer hikes and things like that with my family. And even just shopping with friends, especially if you're just constantly going from one place to another, I think energy levels especially I won't feel so drained and it'd be easier to keep up with them

Because I have a 1-year-old niece that I want to be able to sit on the ground with, chase her around, and not feel as if I'm out of breath, or that I can't

(n = 7)

I strongly disagree with that. I don't have any family members or friends that I know of that run marathons or triathlons or anything of that nature

Be able to keep up with family and friends, strongly disagree. Didn't affect me whatsoever

*l) Be able to find clothes I feel good in**(n = 17)*

At this point I use like 1×–2× plus sizes, and just in general plus sizes are harder to find and especially if you want to find clothes that you actually enjoy it's a lot, losing weight would put me back into the more regular range of clothing sizes and therefore just make it easier

I would put agree because it is sometimes hard to find plus-size clothing. So, I would do agree. I mean I've had luck at Ross and stuff like that. But, yes, it would be nice to not just have a smaller section at the store

Because some things I can't find in my size. Sometimes it's disappointing but I don't let that get me down

(n = 1)

Be able to find clothes I feel good in, I want to go neutral on that... I'm not a fashion maven at all

Table 3 continued

If I lost weight, I would.**Agree/strongly agree****Neutral/disagree/strongly disagree***m) Feel more comfortable in my clothes**(n = 18)**(n = 0)*

Yeah, definitely strongly agree... I feel like sometimes things are fitting kind of weirdly... either it's really baggy or like kind of tight to the point where it's almost not really something I should be wearing... then I'm thinking about it, I'm self-conscious about it. So, that could definitely improve

I like that because you always want to feel good and look good in your clothes, like tuck your shirts in, wear a nice belt. I like that... you don't want anything to be tight or pulling

Feel more comfortable in my clothes. I strongly agree, and that's just because I look at myself in some clothes, and may not feel as comfortable, or want to show or wear them a certain way, because I can see different areas that I'm uncomfortable with

*n) Feel more comfortable in social settings**(n = 13)**(n = 5)*

If I lost weight, I would feel more comfortable in social settings. Strongly agree, because then I would no longer be the biggest person in the room

Strongly agree. It's just a confidence level. If you lose weight, you just feel more confident. You don't have to worry as much about how you look because you don't even think about it

I would strongly agree only because it kind of goes back to the bending and moving around, so being able to comfortably sit on a chair that everybody else is sitting, or being able to stand for a period of time and talk, or bending down, or simple things like that are very hard for me

Feel more comfortable in social settings. Yeah, strongly agree. I feel like if I lost weight, maybe I wouldn't be as sweaty in social situations, in social settings, especially indoor ones where the air conditioner sucks

I'm neutral with that one... I mean, even when I was a little heavier, I would still... I was still able to go around my social setting and be fine because, I mean, everybody kind would accept me for who I am anyway, friends, family. I didn't really have that issue being in a social setting

That would be disagree... Whatever setting I'm in I make myself known. My personality just gives it off. My weight doesn't come off like, oh my God, certain stuff like that. And I don't worry about stuff like that

Table 3 continued

If I lost weight, I would.**Agree/strongly agree****Neutral/disagree/strongly disagree***o) Be more social**(n = 8)*

Be more social. I guess I agree, I wouldn't say I strongly agree because I'm pretty social as it is

I put just agree. Only because partly I am naturally just an introvert but also I definitely think I'd be more comfortable to be out in a social setting more often. Just like around... people I really know well, or even just if I'm meeting new people. I honestly think if I lost weight I'd definitely be more social

I'm pretty social, anyway, so I'm going to say 'agree'

(n = 10)

No, I strongly disagree with that... I don't think that has anything to do with that. Generally, I try to be more social regardless of whether or not I lost weight or I didn't lose weight

I disagree. I'm just a social person. For me, my weight doesn't affect my social life immensely I don't think

This one's more neutral for me, and that's only because I'm already social myself, and I don't feel that if I were to lose weight, that it would be any more so

*p) Be happier**(n = 15)*

But if I were to lose weight and say, back at that medium where I used to be, 'Oh, man, I'd be significantly more confident and significantly happier'

I agree that I'd be happier, and I am happier having lost some

I think I strongly agree with that one, and that's only because I would be happier myself by the way I look and how I feel

(n = 3)

I would go with neutral probably. It's easy to say if I lost weight, I'd be happier, but there's other things that come into play. There's always something to be unhappy about, I guess

I'm going to put a neutral on that... I would definitely be happier that I lost weight. But I wouldn't necessarily say that just because I don't lose weight that I'm going to be unhappier

*q) Feel better about myself**(n = 18)*

Because I don't feel great about my physical, how I am physically. But you know, I feel like I'm a decent person. I feel like I'm pretty smart, so I'm not totally unhappy with myself

Yeah, I always think you feel good like oh, look at me, I lost 20 pounds or I lost 25. You're just more upbeat. You're happier. Your mood's better

*(n = 0)**r) Feel more confident**(n = 14)*

I imagine the more weight I continue to lose, the better I'll feel, the happier I'll be, more confident

Comes back to feeling more comfortable in my body and in my clothes when I'm smaller, so I think results in me just feeling a bit more confident

(n = 4)

I would say I would disagree with that because I think confidence for me personally has nothing to do with weight loss or not... I don't think that if I lost weight that I would feel more confident than where I'm at right now

Feel more confident? Disagree. I'm always confident

Table 3 continued**If I lost weight, I would.**

Agree/strongly agree	Neutral/disagree/strongly disagree
<p>s) <i>Feel more comfortable in my own skin</i></p> <p>(<i>n</i> = 17)</p> <p>Feeling more comfortable in my own skin. I'd say that's an agree. I'm aware of the fact that I would like to lose weight I would say agree, I'm comfortable in my own skin, but I definitely want to improve on weight, lose 20 pounds give or take</p> <p>Strongly agree, I feel that if I lose weight that I would be more comfortable as a person, mentally and physically</p> <p>And feel more comfortable in my own skin? Yeah, definitely agree, for sure, because the more skin you have, the less comfortable it is, and it feels, ugh, it feels like you're just dragging all this extra stuff around. It doesn't feel very comfortable</p>	<p>(<i>n</i> = 1)</p> <p>I'd say neutral on that... I can't say that I'm uncomfortable with my own skin because I have a gut. I would say it really depends on my mood or depends on the situation that I may or may not feel comfortable in my own skin</p>
<p>t) <i>Have a better sex life</i>^a</p> <p>(<i>n</i> = 10)</p> <p>Yes, because it very much affects that. I was doing testosterone for a while. I have to use the little blue pill if I want something to happen</p> <p>Have a better sex life. I would have to say agree, you know, because you got more stamina when you weigh less</p> <p>Strongly agree, and I just think that your libido is definitely a lot better or your sex drive is a lot stronger when you've lost weight and you're not having to think about how you feel or look</p>	<p>(<i>n</i> = 2)</p> <p>I would say neutral on that. I can't say whether or not if I lost weight my wife would say let's have more sex or not. I can't say that the weight loss has anything to do with that or not</p> <p>It would be neutral because my sex life is fine</p>

^aIntroduced by one participant in round 1; then tested with the remaining 12 participants (in rounds 2 and 3)

physician- and self-initiated conversations (*n* = 3) or solely self-initiated conversations (*n* = 3). There were mixed reactions regarding prior interactions with physicians regarding weight and weight loss regardless of who initiated the conversations. The majority of participants (*n* = 14) were open to using medications to aid weight loss. However, they were generally unsure of currently available medications and shared concerns about potential side effects and

costs of medications as well as rebound weight gain upon treatment discontinuation (Table 2).

Cognitive Debriefing of the Patient Assessment Tool

The tool was refined over three iterative rounds of patient interviews; the Supplementary Material presents the final version of the tool. "Feeling Frustrated About Your Weight" was

Table 4 Summary of patient and KOL feedback on weight-loss benefit statements

Item stem (concept)	Patients including in top 5 (<i>N</i> = 18), <i>n</i> (%)	KOL recommendation (<i>N</i> = 4)		Project team decision
		Retain, <i>n</i>	Remove, <i>n</i>	
<i>Be healthier</i>	13 (72)	4	0	Retain
<i>Live longer</i>	10 (56)	4	0	Retain
<i>Feel better about myself</i>	8 (44)	4	0	Retain
<i>Have more energy or stamina</i>	7 (39)	4	0	Retain
<i>Have fewer aches and pains</i>	7 (39)	4	0	Retain
<i>Be able to find clothes I feel good in</i>	7 (39)	4	0	Retain
<i>Be more physically active</i>	7 (39)	4	0	Retain
<i>Feel more confident</i>	6 (33)	4	0	Retain
Be able to bend or move around more easily	4 (22)	4	0	Remove
Improve other health conditions	4 (22)	1	3	Remove
Have a better sex life ^a	3 (23)	4	0	Remove
Feel more comfortable in social settings	3 (17)	4	0	Remove
Feel more comfortable in my clothes	3 (17)	2	2	Remove
Require fewer medicines	2 (11)	3	1	Remove
Feel more comfortable in my own skin	2 (11)	3	1	Remove
Be able to keep up with family and friends	2 (11)	1	3	Remove
Be out of breath less often	1 (6)	0	4	Remove
Be happier	1 (6)	0	4	Remove
Be more social	1 (6)	0	4	Remove
Be able to walk faster or farther	0	0	4	Remove

Note: Percentage based on 13 patients. Italicized text denotes the eight items retained for the final patient assessment tool
KOL key opinion leader

^aIntroduced by 1 patient (round 1) as important and then endorsed by 2 out of 12 patients (rounds 2 and 3) in the top five “most important”

selected as the tool title based on feedback from patients and KOLs. Participants appreciated the introductory statements explaining that myriad factors influence weight management and

acknowledging the importance of lowering the risk for weight-related conditions through small reductions in weight. Participants generally felt that the statement was motivating, informative,

and nonjudgmental, sharing that it validated their perceptions regarding weight and weight loss.

While debriefing item 1, describing the benefits of weight loss, round 1 participants were asked how much they agreed or disagreed with 19 concepts capturing anticipated weight-loss goals. On the basis of participant feedback, an additional statement regarding sex life was added to subsequent interview rounds (Table 3). In each round, after participants provided a response and feedback to each concept, they were asked to identify the “top five” most important concepts. Almost all participants agreed (i.e., selected agree or strongly agree) with the statements that were included in their top five.

Across all three rounds of interviews, participants reported that the open-ended question (“In your own words, why would you like to lose weight?”; item 2) was clear as written and important to include in a tool designed to encourage patient–HCP discussion about weight. No changes were made to this item, and it was retained for the final patient assessment tool.

Participants in all three interview rounds considered the question about prior weight-loss efforts (item 3) to be clear as written and important to include in the tool. No changes were made to the question, but the response options were refined on the basis of feedback from round 1 and/or round 2 interviews and tested in subsequent rounds. This item was retained for the final patient assessment tool.

Participants believed that the question regarding willingness to speak with an HCP about weight (item 4) was clear as written. Even though a few participants assumed that anyone who took time to complete the form was already interested in speaking with an HCP about their weight, they did not feel that the item would be burdensome to complete. No changes were made to this item, and it was retained for the final patient assessment tool.

Across all three rounds of interviews, participants reported that the question about discussion topics with an HCP (item 5) was clear as written and would facilitate patient–HCP discussion regarding weight-management

strategies. No changes were made to the question, but the response options were refined on the basis of feedback from the round 1 and/or round 2 interviews and tested in subsequent rounds. This item was retained for the final tool.

Overall, participants felt that the tool was comprehensive in its coverage of topics that could be discussed between patients and HCPs regarding weight loss. As such, participants did not suggest any additional concepts or items that they believed should be included in the tool. Participants expressed their belief that the tool would achieve its intended purpose of facilitating weight-related discussions between patients and HCPs. Furthermore, they found the tool to be motivating and felt that it would encourage self-advocacy in that they felt validated with little, if any, self-blame.

Tool Finalization

During the second consultation with KOLs, refinements made to the tool between interview rounds based on participant feedback were discussed, and key decisions were made about which of the 19 weight-loss benefit statements should be retained in item 1. The decision was made to retain the weight-loss benefit statements endorsed as most important and relevant by patients and KOLs while also maintaining a smaller number of statements for the brief tool. A total of eight weight-loss benefit statements were retained in item 1 for the final tool. These concepts were consistently deemed important by participants; each was also selected by at least 33% of participants as a “top five” concept and endorsed by all four KOLs (Table 4). No changes were made to any other items.

DISCUSSION

This study aimed to develop a brief, self-completed assessment tool to facilitate communications between patients with overweight or obesity and their HCPs about the impact of excess weight on patients’ lives (as perceived by the patient), paving the way for an open dialogue about treatment options. In addition to items pertaining to patients’ feelings and

experiences related to their weight, the measure includes eight potential benefits of weight loss:

- Be healthier
- Live longer
- Feel better about myself
- Have more energy or stamina
- Have fewer aches and pains
- Be able to find clothes I feel good in
- Be more physically active
- Feel more confident

Respondents are asked to rate their degree of agreement (or disagreement) with each statement “If I lost weight I would...”. To ensure that patients are able to express more personal or unique goals in the assessment tool, it also includes an open-ended statement for completion. Furthermore, the final tool includes information on obesity to both inform and support users (patients and HCPs), as well as historical information on past weight-loss strategies and patients’ desires for future strategies to guide patient–HCP discussion.

On the basis of KOL feedback and patients’ prior experiences, awareness and acceptance of the tool by HCPs likely to come in contact with it (i.e., likely to be presented a completed tool by patients) will help maximize the utility of the tool and should potentially be considered a prerequisite to its dissemination. As part of this adoption, HCPs need education about obesity as a chronic, adiposity-based disease and available resources to fully support the intended goal of the tool. It is anticipated that a multistep and multi-sourced communications plan will be needed to ensure sufficient and successful HCP adoption and patient access.

Limitations of this study are acknowledged. Participant recruitment was purposeful, aimed at obtaining a mix of participants to obtain a sample that generally reflects the intended end user of the patient tool, although representativeness of the population at large cannot be assured with the intentional small sample. Given the wealth of qualitative interview data available from development of the IWQOL-Lite-CT and the IWDAQ, as well as input from KOLs, the focus of the interviews in this study was on refining the draft tool rather than de novo concept elicitation. As such, a large sample

would have been unnecessary because major issues with the tool should be revealed with just a few interviews [25]. Sample sizes of 5–15 have been suggested as a typical range [26]. A sample size of 18, including three rounds of interviews with six participants each, was considered appropriate for this study.

Another potential limitation is that views of both patient and KOL participants may not be fully representative of the populations from which these research samples were drawn. For example, participants who provided feedback on the tool expressed both a desire to lose weight and willingness to participate in the study. As such, on average, they may have been more motivated to lose weight than many individuals with overweight or obesity. Finally, feedback obtained from four KOLs cannot be considered representative of all HCPs or experts in the field of obesity.

CONCLUSIONS

The patient assessment tool is a five-question, self-completed measure, expected to require less than 5 min for completion. The tool was rigorously developed for the purpose of encouraging and facilitating conversations between patients and their HCPs. On the basis of participant feedback, the tool is expected to foster patient self-advocacy for individuals with overweight or obesity by giving them an opportunity to define their weight-management goals and discuss these, along with various medical interventions, with an HCP. Additionally, this tool can capture important information for HCPs by providing insight into patients’ past challenges and future goals with regard to weight management, thus paving the way for a patient-centered and personalized strategy for discussion.

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Compliance with Ethics Guidelines. The study materials and protocol were reviewed on ethical grounds by the institutional review board of RTI International, and the study was deemed exempt from full review. The study was conducted in accordance with the 1964 Declaration of Helsinki and its later amendments. All participants provided verbal informed consent to participate in the study and have their responses and characteristics published in summary form, which was considered sufficient for a non-interventional interview study.

Data Availability. The datasets generated and analyzed during the current study are not publicly available to protect participant confidentiality.

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