

## TECHNICAL REPORT



Behavior, Psychology and Sociology

# Technical report: an online international weight control registry to inform precision approaches to healthy weight management

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**BACKGROUND:** Personalizing approaches to prevention and treatment of obesity will be a crucial aspect of precision health initiatives. However, in considering individual susceptibility to obesity, much remains to be learned about how to support healthy weight management in different population subgroups, environments and geographical locations.

**SUBJECTS/METHODS:** The International Weight Control Registry (IWCR) has been launched to facilitate a deeper and broader understanding of the spectrum of factors contributing to success and challenges in weight loss and weight loss maintenance in individuals and across population groups. The IWCR registry aims to recruit, enroll and follow a diverse cohort of adults with varying rates of success in weight management. Data collection methods include questionnaires of demographic variables, weight history, and behavioral, cultural, economic, psychological, and environmental domains. A subset of participants will provide objective measures of physical activity, weight, and body composition along with detailed reports of dietary intake. Lastly, participants will be able to provide qualitative information in an unstructured format on additional topics they feel are relevant, and environmental data will be obtained from public sources based on participant zip code.

**CONCLUSIONS:** The IWCR will be a resource for researchers to inform improvements in interventions for weight loss and weight loss maintenance in different countries, and to examine environmental and policy-level factors that affect weight management in different population groups. This large scale, multi-level approach aims to inform efforts to reduce the prevalence of obesity worldwide and its associated comorbidities and economic impacts.

**TRIAL REGISTRATION:** NCT04907396 (clinicaltrials.gov) sponsor SB Roberts; Tufts University IRB #13075.

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## INTRODUCTION

Obesity is a worsening global public health crisis that is a major driver of the rising prevalence of chronic diseases and increases in health care spending [1, 2]. Despite frequent weight loss attempts by individuals with obesity [3], rates of success are generally low and weight regain is common [4]. These results suggest an incomplete understanding of factors that optimize obesity treatment and how these factors vary across different population groups and environments.

In efforts to learn from individual experiences with weight management, several registries have collected information from people who succeeded in long-term weight loss. The largest of these registries is the National Weight Control Registry (NWCR, <http://www.nwcr.ws>). The NWCR was established to identify core behavioral factors associated with long-term weight loss maintenance in U.S. adults. In that cohort, maintaining high levels of exercise, self-monitoring weight and weight management behaviors, and consuming a diet lower in fat have been

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**Table 1.** International sites requesting to participate in the registry, and example recruitment strategies for U.S. registry participants.

Partnering countries	
Australia, Bahrain, Brazil, Canada, China, Egypt, Finland, France, Germany, Greece (currently recruiting), India, Italy (currently recruiting), Jordan, Kuwait (currently recruiting), Lebanon, Morocco, Palestine, Portugal, Qatar, Saudi Arabia, Sweden, Tunisia, UAE, USA	
U.S. National-Level Recruitment	U.S. Local Recruitment
Traditional and social media	Research institute recruitment databases
Obesity Action Coalition	Affiliated hospital primary care networks and weight management centers
Black Girls RUN	Participants in ongoing and new randomized clinical trials relevant to obesity
United Health Group	USDA Extension partnerships
	CTSI community engagement

CTSI Clinical and Translational Science Institute, USDA United States Department of Agriculture.

identified as core behavioral factors associated with weight loss maintenance, and behavioral consistency, eating breakfast, and low dietary variety are identified as additional factors [5, 6]. The NWCR also enabled the identification of subgroups, including a weight-stable exercising group, and a smaller group that relied primarily on diet for weight loss and weight loss maintenance [7]. While such information is important, the NWCR is nearly 30 years old and, consequently, was not designed to capture several dietary and psychosocial factors more recently identified as potential contributors to weight regulation [8]. Further, the majority of NWCR enrollees were middle-aged, higher income, non-Hispanic White women, and very little is known about predictors of weight loss maintenance in men or in individuals from different age groups, ethnic and racial groups, socioeconomic brackets, and education levels. Previous studies have documented that existing weight loss interventions are less effective for historically marginalized populations compared to White, affluent groups [9, 10]. There is an urgent need to develop effectual weight loss programs for groups disproportionately burdened by obesity. Furthermore, enrollment in the NWCR was restricted to individuals who had lost  $\geq 13.6$  kg and maintained that weight loss for at least 1 year. Therefore, it did not collect information on weight management strategies from individuals who lost  $< 13.6$  kg, did not maintain their weight loss, or did not lose any weight at all. In particular, information on unsuccessful weight loss attempts is needed to compare with predictors of successful weight loss and weight loss maintenance, as these comparisons are critical to informing precision approaches to scalable weight management [11]. Outside the United States, other national registries have been established but as summarized in a review have collected limited information on small numbers of participants [12]. Thus, very little is currently known about successful weight management strategies within and across the world's diverse cultures.

We describe here the formation of the International Weight Control Registry (IWCR, [www.internationalweightcontrolregistry.org](http://www.internationalweightcontrolregistry.org)). The overarching goal of the registry, which is intended to be a hypothesis-generating longitudinal initiative, is to identify successful weight management strategies in individuals and different population groups. The primary outcome is weight change. Participants will provide data on weight, behavioral factors, food culture, economics, psychology, social conditions, and the environment using traditional research methods and remote monitoring. They also will be given opportunities to provide qualitative information in an unstructured format on additional topics they identify as relevant. To ensure that the registry remains on the cutting edge of obesity research, the IWCR Group will review registry findings and perform an ongoing review of the literature to identify novel topics for additional data collection. To better inform the next-generation of intervention research, the IWCR aims to include data on wide-ranging experiences with weight management in underrepresented groups.

## METHODS

### Registry overview and approval

Adults  $> 18$  years are eligible to enroll in the secure online IWCR platform ([www.internationalweightcontrolregistry.org](http://www.internationalweightcontrolregistry.org)) if they have attempted weight loss (including successful and unsuccessful attempts, with or without weight regain) or are interested in attempting weight loss for the first time. The registry's inclusion criteria are intentionally broad to allow for comparisons between individuals with differing levels of success in weight loss and weight loss maintenance. An earlier beta version of the platform used to develop the registry and initiate international sites (see below) restricted enrollment to individuals who reported at least 5% weight loss. The institutional review board (IRB) at Tufts University serves as the single IRB with a reliance agreement for participating U.S. researchers from other institutions for both the beta site and the IWCR platform. Informed consent is conducted online prior to enrollment using the registry platform and includes language that conforms to the European Union's General Data Protection Regulation criteria (which tends to be more stringent than other regulatory bodies and therefore provides a standard that can be accepted in other international sites). All international research collaborators, irrespective of their country, have to also obtain IRB approval for study participation from their local IRB.

### Recruitment and retention

An initial list of countries requesting to participate in the IWCR and planned U.S. outreach initiatives are provided in Table 1. The international sites were identified as sites with active obesity researchers who were contacted by a member of the U.S. team and had at least 1 meeting with them, after which they confirmed their interest in participating. After reviewing all the planned questionnaires for local suitability, all local research teams were required to obtain their own IRB permission, after which they were invited to enroll at least 50 participants in the beta site to gain experience with the registry. The goal was to use this work to determine if revisions would be needed for cultural suitability initially using an interviewer-administered process in the local language, with the potential to add questionnaires on specific local issues. Three international sites (Kuwait, Greece and Italy) were lead by scientists with the capacity to conduct pilot studies without the need to first fund local activities. Based on this experience, these sites will migrate to using the IWCR platform for future participants. Other sites are at different stages of capacity building for IWCR engagement at the present time.

Concerning recruitment of participants, due to the following factors, obtaining a normative sample of participants from each country in the registry is not initially feasible: 1) the eligibility criterion that individuals must be interested in weight management; 2) the estimated average time commitment for participation is 70 min for completion of core activities; and 3) participants need access to a smartphone, tablet, or computer to enter data into the registry. However, to prevent biases resulting from the recruitment of very specific subgroups, recruitment activities of participating research sites will target *as many diverse sources as possible* by implementing strategies at the local and national levels of each country. Furthermore, tracking activities and data analytics will identify groups that are underrepresented in the registry, thereby informing additional targeted recruitment efforts. In the U.S. recruiting a diversity of participants into the registry is being approached by collaborating with researchers who have established relationships with community and agricultural extensions to target rural and Latin representation, and with researchers

who have established partnerships with local, regional, and national organizations such as Black Girls Run, the Council on Black Health, and the Divine 9 Fraternities and Sororities to target Black representation.

Participant engagement and retention activities will be implemented to maximize follow-up participation. As part of our communications strategy, we will produce a regular email newsletter, host webinars by study investigators on health-related topics that do not overtly influence participant weight management strategies, share new information first with registry members, and create private Facebook groups for moderated communication with participants. Examples of newsletter topics designed to be engaging without intervening in participant weight are 'The Citizen Science of Weight Loss' and 'Is Holiday Weight Gain Real?' In addition, a small stipend will be offered to participants when permitted by funding, to serve as compensation for time spent to complete registry activities, and a future Spanish language version is planned.

## Overview of current data collection

- Questionnaires on a comprehensive set of constructs and measures thought to be relevant to the development of obesity, weight loss, and weight loss maintenance will capture data upon enrollment on a broad variety of factors. A subset of questionnaires and other measures will be repeated annually to track participants over time. Similar to the National Institutes of Health-supported Accumulating Data to Optimally Predict Obesity Treatment (ADOPT) initiative [13], measures in the IWCR span behavioral, environmental, psychosocial, and biological domains. In addition, the COVID-19 pandemic is contextually relevant due to potential effects on eating behaviors and physical activity as well as weight-related norms and psychological factors, and specific questions are included that may assess the impact of the COVID-related changes in lifestyle, stressors, and eating behaviors.
- Data will be requested from wearable sensors, devices, and programs that participants use as part of their weight management activities, including wearable activity monitors, Wi-Fi-enabled scales, and online food trackers.
- Relevant data on the local environment and weather patterns identified by zip code will be collected using information that is readily available online. These data include social factors, political factors, and built environmental factors.
- Open-response format questions are inserted at intervals throughout the questionnaires, to allow for additional comments triggered by thoughts occurring during different areas of questionnaire completion. These data will be analyzed using natural language processing to identify novel insights into participant sentiment, emotion, and themes identified through topic modeling. The continuous data from sentiment analysis and topic modeling can be paired to the Likert style responses on validated questionnaires, providing novel opportunities for hypothesis generation, and identify new areas for future data capture [14, 15].
- Sub-studies will be conducted to evaluate detailed measures of dietary intake, physical activity and sleep, in addition to the home and local environment. These measures may be implemented registry-wide in subsequent years.

## Questionnaires

Questionnaires for implementation in this first version of the IWCR are summarized in Table 2. They are consistent with ADOPT recommendations where appropriate but differ for some constructs due to the online nature of questionnaire completion and the design of the registry for both domestic and international use. Most questionnaires have previously been validated, while some are investigator-created to fill specific areas where no validated instrument exists.

## Device integration

IWCR participants will be given the opportunity to opt in for sharing data from wrist-worn activity trackers, wireless Wi-Fi scales, and built-in and third-party physical activity and food tracking mobile applications (apps) on iOS and Android devices. For those who opt in, software from Validic Inc. (Durham, NC, USA) will be used to capture and store device data in real time from iOS and Android devices. The collection of data from wearable devices and the tracking activities that participants do as part of their personal weight management activities represents a unique strength of the IWCR relative to previous obesity-related registries.

## Free-text responses

The collection of qualitative, free-text responses to open-ended questions placed at intervals throughout the IWCR survey will provide the opportunity for participants to offer more detailed and or nuanced information, and allow for sentiment analysis, word frequency and topic modeling using natural language processing [14, 16, 17].

## Sub-studies

Sub-studies will be used to conduct in-depth assessments of behavioral and environmental factors potentially related to obesity and weight management. All sub-study assessments will use standardized methodology and, in the case of sensor data, the same model of equipment for each participant. In initially planned sub-studies (Table 3), 200 participants will be provided with a wrist-worn activity tracker and Wi-Fi scale for a pilot evaluation of the utility of this standardization for registry-wide use [18–20].

Sub-study participants also will complete dietary recalls on weekdays and weekends using the multiple-pass, interviewer-administered 24-h recall method [21]. In the U.S. analyses will be performed using Nutrition Data System for Research software (Version 2018 or latest, Nutrition Coordinating Center, University of Minnesota, Minneapolis, MN, USA), and dietary intake data will be used to calculate a Healthy Eating Index score [22]. In international sites, the same 24-h recall method will be used to capture data, and the most relevant local food database will be used to calculate nutrient intakes.

The initial sub-study participants also will be asked to provide their home address for objective assessment of their immediate neighborhood environment. The Microscale Audit of Pedestrian Streetscapes (MAPS) [23, 24] direct observation instrument will be used to classify the home neighborhood environment using Google Street View without any direct burden to participants [25]. The MAPS assessment is completed along a 0.25-mile street network originating at the participant's home and headed toward a predefined location. We will define this location as the nearest grocery store (i.e., supermarket, local grocer, or corner store) and use the "shortest distance" option in Google Maps for creating the route to be audited. The MAPS survey includes sections on land use/destinations (e.g., parking, housing, food-related land use, retail, recreation), route (e.g., public transit, streetlights, street amenities, neighborhood aesthetics), segment (e.g., presence and condition of sidewalks, walking paths, bicycle lanes), crossings (e.g., intersection control, intersection type), and presence of cul-de-sacs.

## Harmonization of data collection across countries

Collection of data from countries outside the United States represents an important opportunity to increase understanding of the different ways in which healthy weight management can be achieved and sustained. Where possible, questionnaires that have been validated in both the United States and other countries were selected for use. Over time, website translations for additional languages are planned with appropriate technical translation and validation of the translations to ensure they are psychometrically sound [26]. Based on feedback from the pilot data collection step for international sites described above, questionnaires may be revised or increased based on relevance to the local context. To the extent possible, however, core questionnaires will be implemented across all sites to allow for future analyses of multi-site data.

Concerning dietary intake, multiple pass, the interviewer-administered 24-h dietary recall method used in national surveys in the U.S. [27] will be used to capture dietary energy, nutrient intakes, and meal patterns and timing in a subset of participants. This method employs five formal steps designed to enhance accuracy of the reported food intake. Training in the administration of the method will be conducted in English by the IWCR dietary core team at Tufts University, which has expertise in collection and interpretation of dietary data. To allow for national variations in the composition of selected foods, the database used with the recall method to calculate nutrient intakes will be country specific.

## Data security and management

The IWCR database is housed on a secure REDCap-based platform at the University of Alabama at Birmingham (UAB). IWCR participants provide electronic informed consent, enroll, and complete all questionnaires and open responses directly within a customized REDCap project optimized for general population user experience. Participants are provided with a unique survey queue link that allows them to access and complete surveys at their desired pace (surveys can be saved and continued as needed). To improve survey completion rates, the database has been programmed to

**Table 2.** Phenotypic profile for International Weight Control Registry participants with core questionnaires and data from wearables<sup>a</sup>.

<b>Biological Domain</b>	
<b>Construct</b>	<b>Measure(s)</b>
Demographics	Date of birth, sex, race/ethnicity
Anthropometry	Self-reported weight, weight history (current, highest adult, and lowest adult)
Overall health and well-being	36-Item Short Form Health Survey [30, 31]
<b>Behavioral Domain</b>	
<b>Construct</b>	<b>Measure(s)</b>
Usual dietary intake and diet quality	Meal patterns (adapted from Sugar-Sweetened Beverage and Eating Away from Home Questionnaires [32])
Physical activity and sedentary behavior	Data capture from participant-owned or study-provided fitness trackers and smartphones via Validic, Inc. [33] International Physical Activity Questionnaire [34]
Sleep behavior	Medical Outcomes Survey Sleep Questionnaire [35] Morningness-Eveningness Questionnaire [36]
<b>Environmental Domain</b>	
<b>Construct</b>	<b>Measure(s)</b>
Objective food and physical activity environment	Home zip code
Self-reported food and physical activity environment	NEMS-P [37] and NEWS-A [38]
Socioeconomic and social status	Educational attainment, annual household income, food security
Social environment	Household size, marital status, BMI of spouse/partner weight-related social norms
Social support	Social Support Questionnaire [39]
<b>Psychosocial Domain</b>	
<b>Construct</b>	<b>Measure(s)</b>
Food cravings	Trait Food Craving Questionnaire – Reduced [40]
State affect	Positive and negative affect [41]
Dietary restraint, disinhibition, and hunger	Three-Factor Eating Questionnaire [42]
Stress reactivity	Perceived Stress Reactivity Scale [43]
Motivation for weight management	Treatment Self-Regulation Questionnaire [44]
Motivation for exercise	Exercise Identity and behavioral regulation [45, 46]
Delay discounting	5-trial adjusting delay task [47]
Life course trajectory	Life History Theory Questionnaire [48]
Self-compassion	Self-Compassion Scale – Short Form [49]
Self-stigma	Weight Self-Stigma Questionnaire [50]
Centered identity – resilience	Psychological Well-Being – Short Form [51]

<sup>a</sup>Citations are given for published questionnaires.

**Table 3.** Planned sub-study constructs and measures<sup>a</sup>.

<b>Construct</b>	<b>Methods and measure(s)</b>
Measured body weight and body composition (fat and lean mass)	Garmin Index Smart Scale S2 [19]
Usual dietary intake and diet quality	24-h dietary recall [21] and Healthy Eating Index [22]
Objective physical activity, sedentary, and sleep behavior	Garmin vivosmart 4 fitness tracker [18]
Objective food and physical activity environment	Home address with Microscale Audit of Pedestrian Streetscapes completed via Google Street View [23, 24]

<sup>a</sup>Citations are given for published questionnaires.



track participant progress through the surveys and send automated reminders via email or SMS text messaging based on this progress. Additional data capture elements for the IWCR include the ability to collect real-time data from wearable devices and WiFi-enabled scales via a commercial service (Validic Inc.) as noted above, and direct data entry by research staff (not accessible or viewable by IWCR participants) for measures such as 24-h dietary recalls. Data are inspected to remove any implausible results including approaches similar to NHANES (e.g. screening values exceeding the 1st and 99th percentile of age- and sex-specific data).

### Data analysis

The IWCR is a hypothesis-generating initiative, and multiple preplanned analyses on de-identified data will be developed over time. Initial plans for data analysis include comparison of factors associated with weight loss maintenance between different racial/ethnic groups, between urban and rural populations, and between men and women in different U.S. regions. For hypothesis generating initiatives, we will use predictive modeling, unsupervised learning, or supervised learning dimension analysis (e.g. recursive feature analysis) techniques. Multi-level hierarchical modeling techniques coupled with shrinkage estimators, such as Bayesian hierarchical generalized linear models, least absolute shrinkage and selection operator (LASSO), and Elastic net, and machine learning techniques (e.g. random forests), will be explored for predictive modeling [28, 29]. These techniques allow us to simultaneously fit all the factors and rank order variables that are predictive of the success. Training, validation, and test datasets will be created, and cross-validation approaches will be used to estimate the out-of-sample estimate of predictive accuracy of the models. Dimensionality reduction techniques and unsupervised descriptive methods such as principle component analysis also will be explored.

The open-response format questions will be analyzed using natural language processing, which will provide novel insights into participant sentiment, emotion, and themes identified through topic modeling. The continuous data from sentiment analysis and topic modeling can be paired to the Likert style responses on validated questionnaires, providing novel opportunities for hypothesis generation, and identify new areas for future data capture [14, 15].

### DISCUSSION

There is a clear need to better understand the complex interaction of factors that affect the development, prevention, and successful treatment of obesity in individuals and in different populations and subgroups. The IWCR will collect in-depth data on different population groups for analyses to identify novel factors and combinations of factors that support successful weight loss maintenance. By using free-response questions to elicit feedback on additional factors participants perceive, we also anticipate being able to identify as-yet unanticipated avenues for weight management. Overall, the IWCR is anticipated to improve our ability to inform the development of novel and potentially more effective treatments for different population groups.

A recognized limitation of the IWCR is that enrollees will not be a normative sample. This will be addressed by recruiting from many different sources, so that enrollees have a wide range of backgrounds and experiences with weight management. On an as-needed basis, underrepresented population groups will be targeted with more intensive recruiting efforts to support racial and ethnic balance within registry participants. For IWCR substudies, depending on the research question being asked, bias can be reduced by targeting a random selection of registry enrollees for recruitment. Strengths of the IWCR include the fact that it is an online registry, requiring no in-person visits to research centers, and is using validated questionnaires that are part of the NIH ADOPT initiative [13] where possible. While this feature is particularly valuable for participant recruitment during the COVID-19 pandemic, it also will have great utility for recruitment of rural and other remote populations that do not live close to a nutrition research center and thus would not be able to otherwise participate.

### CONCLUSION

With rates of obesity continuing to rise worldwide, there is an urgent need to improve our understanding of the behavioral, psychological, biological, environmental and other factors that influence the development, prevention and successful treatment of obesity. The IWCR was established by a collaborative of obesity scientists to serve the important function of identifying factors associated with successful weight loss and weight loss maintenance in different population subgroups and countries. The IWCR is striving to identify novel factors and generate hypothesis to inform the development of improved intervention approaches that can be tested in clinical trials.

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## AUTHOR CONTRIBUTIONS

SBR and JOH co-founded the IWCR and drafted this manuscript. SBR, JOH, and IWCR executive co-directors SKD and RDS, led project development with support from JO and MCD. SKD, RDS, AEC, AMG and MCD led the process for identifying questionnaires for inclusion in the registry, with input from all authors. AEC also led the recruitment team, and HW supported by study affiliate Lee Busch led the communication team. TSM and SKD led the development of the data collection platform and data management approach. EAO, MY and YMK provided expert feedback on factors relevant to use of the IWCR in different countries.

## COMPETING INTERESTS

The IWCR was launched in the United States with a grant from the NIH awarded to the Nutrition Obesity Research Center (NORC) at the University of Alabama Birmingham (NIH project number 3P30DK056336-19S1, primary sponsor for JOH); a grant from the United States Department of Agriculture awarded to Tufts University (USDA/ARS project number 8050-51000-105-00D, primary sponsor for SBR); a grant from the University of Colorado NORC (NIH project number 2P30DK048520-26, secondary sponsor); and a small, 1-year unrestricted gift from Gelesis Inc. Dr. Roberts founded the iDiet, a web-based behavioral weight loss program ([www.theidiets.com](http://www.theidiets.com)), and is a Board member of Danone. Dr. Hill has ownership interests in Shakabuku LLC. He has received research grants from National Cattlemen's Beef Association and owns a patent for the Energy Gap. He has received consulting fees from Gelesis and has stock options in the company. Dr. Sayer has no financial conflicts of interest directly related to the IWCR. He has received research grants for nutrition and obesity-related studies from General Mills, National Cattlemen's Beef Association, and Gelesis. Dr. Wyatt has ownership interests in Shakabuku LLC and Dr Holly LLC. She has received research grants from Novo Nordisk, Epitomee, National Cattlemen's Beef Association, and Gelesis. She has received speaking fees from Novo Nordisk and a consulting fee from Gelesis and Roman Health. She is the author of the book entitled *State of Slim* that is published by Rodale. She owns a patent for the Energy Gap. Dr. Greenway owns stock in Slim Health Nutrition, Ketogenic Health Systems, UR Labs, Plensat, Energesis and Rejuvenate Bio. He is a consultant to Academic Technology Ventures, General Nutrition Corporation, Basic Research, Novmeta Pharma and Jazz Pharmaceuticals. Dr. Greenway has a shared patent with Melior Discoveries, and he is on the scientific advisory board for Pfizer and Gelesis. The remaining authors have no relevant conflicts of interest to disclose.

## ADDITIONAL INFORMATION

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