Study Protocol

Study Title: Single arm trial of a multi-component commercial digital weight loss

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IRB-1 Study Protocol

Protocol Version # and/or Date: 5/24/2021

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Clinical Trial/GCP Training

Is this a research study in which one or more human subjects are prospectively assigned[1] to one or more biomedical or behavioral interventions[2] (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes[3] (i.e a clinical trial)? Indicate "yes," "no," or "N/A" in the space immediately below.

Yes

Is the study fully or partially funded by the NIH? Indicate "yes," "no," or "N/A" in the space immediately below.

No

Have the required key personnel completed Good Clinical Practice (GCP) Training? Indicate "yes," "no," or "N/A" in the space immediately below. (Note that IRB approval will not be given for NIH funded clinical trials until all required key personnel complete the GCP training.)

Yes

Research Plan

Purpose/Introduction: [State the reason for the study, the research hypothesis, and the goals of the proposed study as related to the research question(s). Provide a clear and succinct summary description of the background information that led to the plan for this project. Provide references as appropriate and, when applicable, previous work in animal and/or human studies. Provide previous UConn protocol number, if applicable.]

[1]The term "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

[2]An intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive/behavioral therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

[3] 3.Health-related biomedical or behavioral outcome is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention, behavioral intervention for psychiatric symptoms); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

The goal of the proposed research project is to evaluate the acceptability and preliminary outcomes of an online multicomponent commercial weight loss program and to understand the relationship between program engagement and outcomes. Technology is changing the way we deliver behavioral weight loss programs and providing a way to extend their reach to wider audiences. Commercial programs that were once completely delivered via in person meetings at brick-and-mortar businesses are now being converted into online programs. WW (formerly known as Weight Watchers)[1] is an industry leader and one of few commercial programs that has significant evidence for efficacy on weight loss.[2-4] Their program currently includes a mobile app that helps people follow the WW SmartPoints Program, rewards for consistent tracking, an online community to connect with other users,[5] and a 24/7 text chat with coaches function.

Our previous research and others reveals that greater engagement in an online group-based weight loss program is associated with greater weight loss. We have found that an online group coaching program paired with a calorie tracking mobile app is effective at producing weight loss. WW is testing a new comprehensive program that involves an updated program paired with virtual workshops lead by a trained WW coach. They have agreed to fund us to perform a one-arm trial of their new comprehensive program that includes a holistic approach to healthy lifestyle (activity, diet, and mindset). Findings will inform the continued development of this new program. Our aims are as follows:

1. To examine the preliminary outcomes and acceptability of a multicomponent online commercial weight loss program that includes a mobile app, weekly virtual workshops, and an online community. Preliminary outcome is defined as weight change from baseline to 3 and 6-months. Secondary preliminary outcomes include changes in diet quality, physical activity, quality of life, sleep quality, and food cravings from baseline to 6 months. Acceptability of each program component and the overall program will be evaluated at 6 months.
2. To examine whether greater app use, greater engagement in the online community, and engagement with a higher number of peers (in the online community) predict greater weight loss at 3- and 6-months.
3. To examine the associations between total use of program components (and each individual program component) and change in weight. We hypothesize that greater use of program components (individually and total) will predict greater weight loss.

For EACH Participant Population State the Number of Participants to be Enrolled and Screened and/or the number of participant records reviewed (including, HIPAA covered health records and FERPA covered school records), if applicable: [State the total number of participants/records to be enrolled and, if enrolling more than one participant population, describe the total enrollment for each. Tip: consider attrition and the number of participants who may fail screening. Use of a range may provide flexibility. Note that the range must be justified in the **Justification of Sample Size section below**.]

The total number of subjects that will be enrolled into the intervention will be 150. It is estimated that we will screen 2,000 participants to achieve this recruitment goal. Since the initial contact is via an online link, there will be many incomplete responses driving up the number of screened-out participants.

Justification of Sample Size: [For qualitative and pilot studies, describe how the proposed sample size is appropriate for achieving the anticipated results. For quantitative studies, provide a power analysis that includes effect size, power and level of significance with references for how the sample size was determined. Explain the rate of attrition and possible number who fail the screening, with references as appropriate.]

The number of subjects to be recruited for this study is approximately 150. Assuming 15% attrition, 127 participants will complete the study. With α=0.05 and N=127, and assuming SD=6.0% (based 6-month weight loss in the online condition of our recent weight loss trial), we will have 80% power to detect mean 6-month weight change of ±1.5% or greater using a two-sided one-sample t-test.

Enrollment of UConn Students and/or Employees: [Will UConn students be enrolled? If so, describe if these students include those who any key research personnel teaches, or for whom any key research personnel has responsibility. Will UConn employees be enrolled? If so, describe if these employees report to any key personnel. For each group, explain why this population is *necessary* to the study. Tip: convenience is not sufficient justification.]

UConn students and employees may be enrolled if they meet eligibility requirements and are interested in completing the study. Students and employees directly reporting to key personnel on this project will be excluded from participation.

Enrollment of Key Personnel, Spouses or Dependents/Relatives: Will study key personnel, spouses of key personnel, or dependents/relatives of any key personnel be enrolled in the study? If so, describe and provide justification.

No.

For EACH Participant Population Describe Screening Procedures, if applicable: [Describe when participants will be screened and how this will occur. Include copies of all screening forms and related documents. Describe procedures to notify participants of the screening result, if applicable. Provide a copy of the screening instrument.]

We are recruiting overweight and obese individuals of all races and ethnicities, income, and education levels between the ages of 18 and 75 years in the United States. Participants must have regular home Wi-Fi connectivity.

Anticipated Study Time Frame: [Describe the estimated time frame of the study from anticipated start to anticipated finish. If the study will occur in more than phase include these in the time frame. Use of a table is often helpful.]

Project Time Frame:
This study will last for approximately 1 year and will include the following components:

Month	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct
Start-up	X	X										
Recruitment			X	X	X	X						
Intervention					X	X	X	X	X	X	X	X
Follow-ups								X	X	X	X	X
Data manag	X	X	X	X	X	X	X	X	X	X	X	X

ement and analyses												
Final Report												X

Participant Time:
Participants will be in the study for approximately 7 months, which will include the screening phase, a baseline phase, a 6-month intervention, a 3-month follow-up survey, and a 6-month follow-up survey.

Study Phase	**Time**
Initial Screening Survey (5 min)	5
Telephone Screening (30 min)	30
Baseline (65 min total) Scale/app set-up (15 min) Online survey (40 min) NDA acknowledgement (10 min)	65
Intervention Pilot (24 wks)/15 min/day Virtual workshops (24 wks)/30-60/day	1,080-1,800
Follow-up surveys: 3-month online survey (20 min) 6-month online survey (40 min)	60
Total	1,240-1,960 minutes (approx. 21-33 hrs)

Design, Procedures, Materials and Methods: [Describe the study design, including the sequence ll study procedures. Experimental procedures should be clearly described and labeled as such. If the study uses control or experimental groups, or different treatment arms, clearly describe what participation will be like for each of the groups or study arms. Tip: describe procedures in the order conducted, where they will be conducted and how long they will take to complete. The IRB strongly suggests that investigators incorporate *flexibility* into the study design to accommodate anticipated events (i.e. explain how missed study appointments can be made up by participants). If this study offers treatment for the participants' condition, complete the Treatment Study Supplemental Form (IRB-1C) and attach it to this application for review. Use of a table is often helpful here.

Study design: Participation starts with an initial survey, telephone screening, a 2nd survey to collect baseline assessment data, and acknowledgement of a Non-Disclosure Agreement with WW. Eligible participants will then complete an on-boarding process, which includes intervention platform set-up/invitation and scale set up. Participants will then complete a 6-month intervention, a 3-month survey, and a 6-month survey.

Recruitment

Recruitment methods will include strategies used in our previous remote trials,[7] online recruitment will be used with ads posted on Facebook and Instagram, recruitment messages posted in Facebook groups and Craigslist throughout the US, and Research Match which connects volunteers to research studies.[8,9] To meet our 25% goal of reaching males, we will also recruit on Reddit, where 74% of users are male.[10] Facebook group recruitment consists of study staff posting recruitment messages in large, public Facebook groups in cities and towns around the country with even distribution in urban, suburban, and rural areas. To bolster male recruitment we will recruit more aggressively on Reddit via paid ads and via relevant subreddits. To bolster minority recruitment, we will target Facebook neighborhood groups in the 10 metro areas with the highest concentration of minorities.[11] We have met recruitment milestones in our weight loss trials (N=161;[12] N=240[13]; N=328[14]).

A REDCap link will be included with our recruitment materials. Participants will be instructed to click the link to complete the screening survey to be considered for the study. Additional strategies that we may or may not use depending on recruitment flow include:

- Electronic recruitment: online such as, Twitter, newsletters, intranet messages, emails, and other online locations and platforms as needed;
- Connecting with large businesses to get our ad and/or flyer e-mailed to their staff and students;
- WW will email our flyer to customers with a lapsed WW membership;
- Qualtrics recruitment panel: Participants on the Qualtrics panel meeting inclusion criteria will be recruited for this study.
    - On the first page of the survey, they will read a brief introduction about this project and if they complete the survey, they will receive Qualtrics incentives regardless of participation in this trial.
    - If they decide to hear more, they will click forward to the next page, which will be our information sheet.
    - If they would like to participate in the trial after reading that sheet, they will click forward to the next page and start the survey.
    - Participants who provide their email will be contacted by the study team for the telephone screening.

To get a representative sample for this study, it is possible we will have to cap certain groups in order to allow room for other groups (i.e. stop enrolling white women in order to allow enrolling more males or other people of various ethnic/racial backgrounds). In that event, we will send participants generic wording via email (included in accompanying documents) letting them know that we are looking for people with specific characteristics and can only take a certain number of people who have similar characteristics. If they want a further explanation, we will refer them to email Dr. Pagoto to have a more detailed conversation about this decision.

Screening

Participants will complete screening procedures online and over the phone since they may be located anywhere in the US, not just local. We will post online recruitment ads that will contain a link to the informational sheet and an online survey containing the initial screening questions. The initial screening survey will first have a description of the study and will then have the eligibility questions. If they are eligible to proceed they will be contacted by the study team to book a telephone screening call to review the study in more detail, talk about what it means to be a participant in a study, go over the consent form, ask additional screening questions, and provide contact information. The next step in the screening process is to complete an online survey about medical history, lifestyle, and wellbeing. We will not require PCP approval since we assess

exclusionary medical conditions during the screening process. If conditions are reported that might put the participant at risk during the intervention, they will be excluded. WW does not require medical clearance from adults signing up for their commercial weight loss program, thus this does not present more risk than potential participants would experience if they signed up for WW on their own. After the online survey, participants will electronically sign a Non-Disclosure Agreement with WW.

Non-Disclosure Agreement (NDA): Because what is being studied is a new program not yet available to the public, WW is requiring all participants to sign an NDA prior to enrollment into the study. UConn staff will send the participants a link to the NDA through REDCap. Participants can read and review the NDA from there. At the bottom of the page, they will select a button with either the option "I have read this agreement and understand and agree with all of its terms and conditions" or "I do not agree to sign this NDA and therefore withdraw from participating in this study". We will also have the participant's enter their first and last name, date, and contact information if they do agree to the NDA. UConn staff will send both participants and WW a copy of the electronically acknowledged NDA. Participants can choose to not sign the NDA if they are uncomfortable with it, but they will not be able to participate in the study. Participants can contact us if they have any questions, and, if necessary, we can escalate those to WW to help participants make an informed decision.

Participants will need to complete both surveys, telephone screening, electronically sign the NDA, and provide the study team with a baseline weight to confirm BMI (done will scale we ship to them) before being enrolled into the intervention.

Ineligible participants will be notified by the research assistant or coordinator that they do not meet criteria for the study. This will be communicated via e-mail if the reason is not sensitive (i.e. taking exclusionary medication). If the reason is sensitive (i.e. high depression score, suicidal ideation, presence of BED) staff will call them to let them know. In the conversation, staff will use a generic response about how their pattern of responses is not a match to our eligibility criteria (the examples are provided in additional documentation). If they want to know specifics as to why they were ineligible, staff will refer the participant to email the PI so they can have a more detailed discussion about eligibility. This is being done to avoid upsetting participants and letting Dr. Pagoto, a clinical psychologist, handle communication of more sensitive information.

Once the participant completed the telephone screening, baseline survey, and signs the NDA, UConn staff will confirm the participants addresses in order to get them a study scale. Once that is done, UConn will send that information over to WW and WW will process and ship the scale to be directly shipped to the participant (this step is being done due to the pandemic and our staff working from home unable to ship out scales). This process is not much different than buying a scale from a website. Once the participants notifies UConn staff that they received their scale, UConn staff will reach out to the participants (via phone or email) to help them set up the scale, the app, link scale to the WW app, and ensure that they are able to access the intervention platforms. WW will create the participant logins for the Beta App and the scale. UConn staff will then pass the login information to the participants.

Due to the current COVID-19 Pandemic, the lab is working remotely until it is safe to return to the office. As a result, any phone calls made to participants while our team members are working from home will be conducted via Google Voice. This is an app that gives our staff a different phone number to protect their personal information due to their inability to divert UConn phone lines to personal phones. We will not be recording any phone calls with Google Voice. Participants will be able to reach out to investigators as easily as they can using standard calling. Participants do not need the app in order to contact the lab. It is important to note that some information may be retained on Google's active servers temporarily for

billing UConn staff or other business purposes, and residual copies may remain in Google's backup systems. Anonymized copies of call record information, with no personally identifiable information, will be retained on Google systems to meet reporting and auditing requirements. However, this is no different than any standard phone plan. We will ensure all information in the app pertaining to each participant is deleted after the study is over.

Intervention

The 6-month intervention includes the use of three components: WW's mobile app (Beta version of new program) weekly group virtual workshops, and a private Facebook group.The WW weight loss curriculum involves: self-monitoring of weight, dietary intake, and physical activity; making dietary changes; increasing physical activity; and learning behavioral strategies to manage these goals. Each week, participants will set goals and weigh in. Participants will be encouraged to use the app daily. WW staff will monitor all app use and Facebook use. Participants will be enrolled in cohorts. Once they confirm a day and time that they can attend the weekly virtual workshops, we will give them a start date and groups of participants approximately 20 or more will start at the same time.

WW Beta app – After downloading the WW Beta app by receiving a special link and access code, members will complete a personal assessment to determine which food plan to follow. They will then be guided on how to use the app and start their food plan. Members can switch plans at any time. The app assigns each member a personalized SmartPoints budget that consists of daily SmartPoints. SmartPoints is the WW system used to take complex nutritional data and summarize it in a simple number that is easy for users to understand. The app will track daily their SmartPoint Budget and is how users keep track of their daily dietary intake and physical activity. The app also has other features (e.g., provides recipes tracking sleep with a synced fitness device).

Virtual Workshops. Virtual workshops will be offered through Zoom. Links to Zoom virtual workshops will be accessed either through a link in the WW app, or in emails to study participants (sent by WW). If participants do not want to join by Zoom, they can call in. Participants will be asked to attend a virtual workshop weekly during the 6-month intervention. WW will offer several days and times for the participants. The workshops last between 30-60 minutes long and are led by a trained WW coach. The workshops are closed to only WW members within this study and will have no more than 20 participants per workshop. The virtual workshops are meant to provide group support to participants. They will discuss progress and setbacks, troubleshoot challenges, help with goal setting, and discuss and learn about various topics surrounding promoting a healthy lifestyle. These will not be recorded. Additionally, participants will have regular, short (~five minute) one-on-one check-ins with their coach in addition to the virtual group workshops.

Milestone Charms. To help retention rates in the study, WW will send participant's milestone charms for hitting a weight loss milestone during the intervention. These charms are small keychains that shows the milestone they have achieved. Participants will receive a weight loss charm if they hit these milestones of losing: 5lbs, 10lbs, 15lbs, 20lbs, 25lbs, 30lbs, 40lbs, 50lbs, 75lbs, 100lbs, 125lbs, 150lbs, 175lbs, and 200lbs. Milestone weight loss is reviewed each week by UConn staff. If a participant has hit a weight loss milestone, UConn sends the information over to WW via OneDrive (which participant, their address, and what milestone) and WW ships the charms out to

participants. This is set-up is the same as the scale shipping to participants. The participants can opt out of receiving charms at any point.

To avoid questions about the app's capabilities taking up a lot of time during the weekly workshops, WW will also hold additional workshops coined 'App Academy' to go over the app in more detail, walk through the functionalities and different features that the app has to offer and answer questions regarding the app. A WW coach leads this and it is optional. Participants can attend, none, one, or all App Academy times that they offer.

During the final workshop of the study (week 24), the WW coach leading the workshop will ask participants if they are interested in participating in market research focus groups sharing their thoughts and experiences about the app and other market-related questions. The participants will be told that this is not a part of this research study and that it is solely for market research for WW. The WW coach will clarify that participating in the market research focus groups does not having anything to do with this research study and it will also not affect their participation or their status as a participant in the study in any way.

Private Facebook Group – In lieu of using WW's online community that gives members an opportunity to receive motivational support from each other, participants will instead be invited to join an optional, private Facebook group. This private Facebook group will allow participants to receive motivational support from each other, but done so in a way that protects their privacy (as WW's community is open to all members). The private Facebook group will be open to study participants only. Participants will not receive any intervention content within the Facebook group. WW will be managing all aspects of the Facebook group. Members can post about their journey through photos, videos, and comments. The Facebook group will have moderator(s) from WW who ensure community standards are adhered to, but this person does not provide weight loss coaching or post any content. UConn staff may be in the Facebook group in order to use Grytics (a software program) to collect engagement data (see DSAF for Grytics information). Participants will have to "opt-in" to Grytics when they join the Facebook group so that we can download their engagement data. They will see a page about what Grytics is and what data we are collecting (their views to posts, reactions, posts, and comments in the group) and then choose to opt-in to it or not. If they do not, we cannot collect their engagement data. It is not required to do this to be enrolled in the study or to join the group.

WW Troubleshooting. If participants need technical assistance with the WW app, they will be able to email WW (clinical.trials@ww.com) to handle any tech-based problem throughout the 6 months.

Weight data collection – Participants will receive a WW Bluetooth scale mailed to them directly from WW. Once the participant completes the telephone screening, baseline survey, and signs the NDA, UConn staff will confirm the participants addresses in order to get them a study scale. Once that is done, UConn will send that information over to WW and WW will process and ship the scale to be directly shipped to the participant. This scale will allow participants to take their weight weekly and at assessments. Weight is logged directly from the scale to the WW scale app, which synchronizes to the WW Beta app where participants can track their weight progress. The scale app is a commercially available app called the WW Body Analysis Scale Tracker. Using a Bluetooth scale will allow for a standard weight measure for each participant with a higher level of accuracy than self-reported weight. Weight is logged directly from the scale to the participants'

WW accounts via Bluetooth. We will receive their weights from backend WW data. In the event that we are unable to get their scale to pair to the WW apps, participants can upload a screenshot of their weight through REDCap. The study team will send the participant a private survey link, and they can upload a picture of their weight displayed on the scale. From there, the study team will open the image, record the weight from the picture into a field in REDCap, and then permanently delete the image from REDCap. If it is the case that REDCap downloads the image onto the staff's computer, they will also permanently delete it as soon as it is recorded in REDCap. Study staff will help participants set-up their scale and check their BMI once the scale is working. If a participant has a BMI under 25, we exclude them from the study and provide baseline compensation. At the end of the study participants will be allowed to keep their scale.

UConn staff does not have direct access to backend data for the WW app, weight, and virtual workshops. However, WW staff will send us all relevant data throughout the study and after the 3- and 6-month assessment points.

Follow-ups:
Follow-ups are completed at 3-months and 6-months after the start of the intervention. Participants will receive an online follow-up survey during their 13th week and 27th week after the start of the intervention. This survey will be a repeat of some of the measures assessed at baseline (indicated in the measures table below) and questions to solicit participants' feedback on the weight loss program. We will also collect weight at the 3-month and 6-month mark.

WW Memberships:
Participants will be given a free WW membership for 6-months so they can access the WW app and virtual workshops. At the end of the study, memberships will end but they will be allowed to use the publicly available WW apps and programs with purchase.

Adverse Events:
Adverse events will be formally assessed at follow-ups by asking a question in the REDCap survey. If participants gain 5% or more weight during the intervention, this will be treated as an adverse event. The participant will receive a phone call from a UConn RC and they will be asked questions about what might be going on with their weight gain. We will also re-assess Binge Eating Disorder (BED) at this time. If BED is present, we will treat it as a study-related AE. We will only re-assess BED once after the telephone screening, even if there are multiple AE's for weight gain. Participants will not be removed from the intervention if they have 5% or more weight gain.

[Describe study procedures for use of interviews or focus groups if applicable. Include details such as how long each procedure will take to complete, who will be asked to participate in these procedures and where these procedures will be conducted. Provide copies of interview and focus group questions/topic areas.]

N/A

[If the study includes *measures, survey instruments and questionnaires (including the collection of demographic data)*, identify each and, if available, provide references for the measures. Describe what they intend to measure (relate to purpose/hypothesis) and their psychometric

properties (e.g., reliability and validity). Identify any that were specifically created for the study and attach a copy for IRB review.]

Data Collected	List of Measures	Screening	Baseline	During Intervention	3m F/up	6m F/up	Method
BMI	Height	X					REDCap
	Weight	X	X	X	X	X	Scale/REDCap
Demographics	Age, gender, income, employment, marital status, race/ethnicity, household composition*	X	X				REDCap
Medical History	Assesses exclusionary medical conditions*	X	X				REDCap
Food Cravings	Food Craving Inventory[16]		X		X	X	REDCap
Sleep Behavior	Pittsburgh Sleep Quality Index[17]		X		X	X	REDCap
Quality of Life	Impact of Weight on Quality of Life-Lite[19]		X		X	X	REDCap
Dietary Screener	The Five Factor Screener[36]		X		X	X	REDCap
Hunger	The Hunger Visual Analogue Scale[37]		X		X	X	REDCap
Self-Compassion	Self-Compassion Scale[38]		X		X	X	REDCap
Habits	Self-report Behavioral Automaticity Index[39]		X		X	X	REDCap
Physical Activity	Global Physical Activity Questionnaire (GPAQ)[21]		X		X	X	REDCap
Wellbeing	The World Health Organization- Five Well-Being Index (WHO-5)		X		X	X	REDCap
Binge Eating Disorder	SCID Interview for BED[23]	X					Interview
Depression	Patient Health Questionnaire (PHQ-8)[24]		X				REDCap
Social Media Use	Social Media Use*		X				REDCap
History of WW Use	History of ever using WW in the past*				X		REDCap
WW App use	Data extraction			X	X	X	File transfer from WW
WW Virtual Workshops	Data extraction			X	X	X	File transfer from WW
Private Facebook group	Data extraction			X	X	X	Grytics
Intervention Feedback	Acceptability, satisfaction, burden*					X	REDCap

* Investigator-derived items

Psychometric properties for non-investigator derived measures:

Food Craving Inventory: The food craving inventory measures food craving through two subscales: subjective cravings and consumption of particular foods (White et al., 2012). The first subscale (subjective) assessed the frequency of subjective cravings for 47 different foods. The second subscale (behavioral) was intended to measure the extent to which participants gave in to craved foods.[16]

Pittsburgh Sleep Quality Index: The Cronbach's alpha is 0.83, demonstrating a good internal consistency (Smyth, 2012). It is noted that previous studies using different populations of older adults have reported high validity and reliability.[25]

Impact of Weight on Quality of Life-Lite: The total score of all five subtype measures of the scale reported a high reliability of 0.96. In addition, IWQOL-Lite-CT Psychosocial scores correlated moderately to strongly with scores on the SF-36 MCS (0.49 at baseline; 0.41 at week 52).[27]

The Five Factor Screener is a survey regarding how frequently someone consumes different food items. This screener has moderate validity suggesting that this screener can be useful to assess intake of various food items.[36]

Hunger VAS: The Hunger VAS (Visual Analogue Scale) is a reliable measure for appetite research. The Hunger VAS asks "How hungry did you feel over the past week" and is composed of a line with words anchored at each end describing the extremes (Not at all hungry, Extremely hungry). Participants are asked to make a mark on the line corresponding to their feelings and quantification of the measurement is done by measuring the distance from the left end of the mark.[37]

Self-Compassion Scale: The Self-Compassion Scale (SCS) is a 26-item measure of self-compassion that is psychometrically valid and theoretically coherent (reliability ranging from .75-.81 and strong construct validity). The SCS consists of six subscales: self-kindness, self-judgement, common humanity, isolation, mindfulness, and over-identified. Subscales are computed by calculating the mean of subscale item responses. A total self-compassion score can be obtained by reverse scoring the negative subscale items (self-judgement, isolation, and over-identification) and computing a grand mean of all six subscale means.[38]

Self-Report Behavioral Automaticity Index: The Self-Report Behavioral Automaticity Index (SRBAI) is a 4-item measure that that is reliable, correlates highly with existing measures (most Cronbach Alpha's between .90-.97), and is sensitive to effects that characterize habits. The 4-items assess whether Behavior X is something... "I do automatically", "I do without having to consciously remember", "I do without thinking", and "I start doing before I realize I'm doing it". Items are scored using a 7-point Likert scale ranging from strongly disagree to strongly agree.[39]

Global Physical Activity Questionnaire (GPAQ): Reliability coefficients were of moderate to substantial strength (Kappa 0.67 to 0.73; Spearman's rho 0.67 to 0.81). Results on concurrent validity between IPAQ and GPAQ also showed a moderate to strong positive relationship (range 0.45 to 0.65). Results on criterion validity were in the poor-fair (range 0.06 to 0.35).[28,29]

SCID Interview for BED: The SCID's severity scales demonstrated substantial internal consistency (all Cronbach's alphas >.80), test-retest reliability, concurrent, and predictive validity.[31]

PHQ-9: The internal consistency reliability (Cronbach's alpha 0.89) and inter-rater reliability (intra class correlation coefficient, 0.94; 95% CI, 0.86-0.95) were high. PHQ-9 has good reliability and at cut off score ≥9, it has good validity to identify depression in primary care. Similarly, the PHQ-8, similar to PHQ-9 (with the omission of one question) is as useful as the PHQ-9 with strong validity and reliability. [32, 30]

The WHO-5 has been found to have adequate validity in screening for depression and in measuring outcomes in clinical trials.[34] The WHO-5 has satisfactory reliability ($\alpha = 0.90$) and convergent and factorial validity.[35]

[If applicable, describe the use of audiotape and/or videotape, provide justification for use and indicate if this is a requirement of participation.]

N/A

[If the study involves use of *deception* or *incomplete disclosure*, explain the reason why this is necessary to answer the research question(s). Complete the alteration of consent section below]

N/A

[Describe opportunities provided to participants to ask questions in order for them to make an informed decision regarding participation.]

Participants are able to ask questions during the telephone screening and the webinar. They may also email the study team at any time.

Data Analysis: [For all studies, specify the analytic techniques the researcher will use to answer the study questions. Indicate the statistical procedures (e.g. specific descriptive or inferential tests) that will be used and why the procedures are appropriate. For qualitative data, specify the proposed analytic approaches.]

We will use Research Electronic Data Capture (REDCap)[33] for data collection and monitoring completion of study assessments. We will use Grytics to downloaded engagement data and upload it to REDCap and the protected UConn server. Co-Investigator/Statistician Dr. Ran Xu will supervise data management and quality control with the assistance from PhD students and post-docs. We will use NVivo 12 (QSR International, Melbourne, Australia) to manage and analyze qualitative data and SAS 9.4 (SAS Inc, Cary, NC) to analyze quantitative data.

Aim 1: We will summarize the use of each component, engagement in the online community and virtual workshops, and answers to questions assessing program acceptability. We will calculate percent weight change from baseline to 3 months and baseline to 6 months. For participants who do not provide weight at 6 months, we will use a baseline observation carried forward method (i.e., assume no weight loss). Secondarily, we will calculate a complete case 6-month weight change. For both the intent-to-treat and complete case estimates, we will use a one-

sample t-test to compare mean percent weight loss to the null hypothesis of no weight change (i.e., 0% weight loss). We will also describe the distribution of weight loss (e.g., median, IQR, range), and will calculate the proportion of participants who achieve clinically significant weight loss (i.e., ≥5%). We will assess changes in diet quality, physical activity, quality of life, external and internal eating, sleep quality, food cravings, and mood using the same approach as examining weight changes.

Aim 2: We will examine associations between total use of program components (and each individual program component) and change in weight, diet quality, moderate and greater intensity physical activity, mood, and quality of life using correlations and linear regression models.

Aim 3: We will examine associations between overall engagement in the virtual workshop swith percent weight loss at 3- and 6-months using correlations and linear regression models, and associations with ≥5% weight loss with logistic regression models.

Inclusion/Exclusion Criteria: [List ALL inclusion and exclusion criteria. Any proposed exclusion criterion based on gender (women of childbearing potential), age, or race must include justification for the exclusion.]

Inclusion Criteria:

- 18-75 years old
- BMI 25-45 kg/m^2
- Has Wi-Fi connectivity at home
- Able to participate in the study in English
- Self-reported desire to lose weight
- Willing to follow recommendations required by study protocol
- Willing to include demographic information (e.g., ethnicity, income and education)
- Lives in the United States

Age justification: Children under 18 require different programming for weight loss and maintenance given their developmental needs. Weight loss is often not indicated for elderly adults and should be medically supervised.

Exclusion Criteria:

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- Pregnant, lactating, or plans to become pregnant during study period
- Bipolar disorder, substance abuse, psychosis, bulimia, binge eating disorder, or severe depression. Binge eating disorder will be assessed using a structured clinical interview during the telephone screening. All other mental health, including other eating disorders, is assessed using a self-report question on the initial screening survey. We will rely on self-report in place of formally assessing all mental health disorders.
- Had bariatric surgery or plans to have any surgery during the study
- Unable to make dietary changes or increase physical activity
- Unable to walk ¼ mile unaided without stopping
- Smoker or use nicotine vape daily

- Participants that are currently, or within the last 6 months, trying to lose weight via a structured weight-loss program (e.g., at a medical center, university, commercial programs)
- Participants who were a member of WW within the past 12 months
- Participants who are involved in any other research studies at this time
- Weight loss of ≥ 5 kg in the previous 6 months
- Reported health problems that make weight loss or unsupervised exercise unsafe or unreasonable (e.g., chronic pain, orthopedic limitations, heart problems)
- Untreated thyroid disease or any changes (type or dose) in thyroid medication in last 6 months
- Taking any prescription medication with known effects on appetite or weight (e.g., oral steroids, weight loss medications such as Qysmia, Contrave, etc.) with the exception of subjects on a stable dose of SSRIs for 6 months
- Chronic/inflammatory gastrointestinal disorders (irritable bowel syndrome is acceptable)
- History of heart problems (e.g., angina, bypass surgery, myocardial infarction, etc.) within previous 6 months
- Diagnosis of type 1 or type 2 diabetes
- Major surgery within the previous 6 months
- Presence of implanted cardiac defibrillator or pacemaker
- History of cancer within past 5 years or current treatment for cancer (completely resected basal or squamous cell carcinoma acceptable if treatment completed more than 6 months prior to enrollment)
- Meets criteria for severe depression on the PHQ-9 (score of >20)
- Hospitalization for psychiatric disorders during the past 12 months
- Not willing to sign an NDA; or indicated they do not want to agree to NDA's terms
- Unable to attend any virtual workshop meeting times
- Does not have an iPhone

[Describe the conditions under which participants may be removed from the study, i.e., noncompliance with study rules, study termination, etc.]

Participants will be withdrawn from the study if: they drop from participation, do not complete all screening procedures or post inappropriate content on the social network. Participants reporting that they would like to withdraw from the study will be given the option to: 1) withdraw from all intervention-related activity and contacts, but still complete the final assessment or 2) withdraw from the study completely with no additional study contact. If a participant becomes pregnant during the study, they will be withdrawn from the intervention, but will be given the option to still complete the follow-up assessments.

Potential Harms/Risks and Inconveniences: [Describe the potential risks to participants (and secondary participants, if applicable) and ***steps taken to minimize risks*** for each participant population. Assess the likelihood of the risk occurring and, if it were to occur, the seriousness to the participant. Types of risks to consider include, but are not limited to: physical, psychological, social, legal, employment, and financial.

Possible risks for being in this study includes: Injury while exercising, breach of confidential information, and discomfort completing measures. The attempt to avoid risks to participants will be addressed by: suggesting moderate intensity exercise to avoid discomfort, pain, or injury. Participants reporting discomfort will be referred to their PCP. Injuries are unlikely to occur since we screen out medical conditions that could make someone prone to injury and we only suggest moderate activity. Moderate-level physical activity is 3.0 - <6.0 METs, which includes activities such as walking briskly (2.5 to 4 mph), playing doubles tennis, or raking. We also provide

participants with information on exertion level and remind them to seek medical attention if there is pain. Tracking data will be stored electronically in REDCap, a network secure data entry program; any data on paper will be stored in a locked file cabinet; and participants will be informed that they may withdraw from the study at any time if they feel discomfort with any of the study procedures.

Participant engagement data (i.e., WW app, Virtual Workshops, weight data) will be continuously collected by WW. Facebook engagement data will be collected through Grytics that study staff have access to through a secure login. The WW investigator will transfer these files via a UConn OneDrive folder which only Kaylei Arcangel and Joseph DiVito access. Kaylei or Joe will save the data to the UConn research drive and delete it from the OneDrive. WW will review by assigning a staff member to read and assess each interaction in the Facebook group on a regular basis. We will also assess for large weight changes to ensure only the participant is using the app. Any privacy-related problems will be brought to the attention of the PI immediately.

[Describe any anticipated inconveniences the participants may experience (such as: their time, abstention from food, etc.).]

Participants will be asked to dedicate up to 33 hours of their time over the course of 7 months to participate in this study.

Instances of threats or harassment in the Facebook group will be handled in the manner below:

Profanity & Vulgarity

- R-rated language
  - Remove all R-rated language used as a form of a personal attack, e.g. “You are a b****” or “F*** you”. These specific words are not permitted at all times: “c***”, “d***”, “c**k”, “b**** f***”, “m*****f*****”.
- “Shit”
  - Permit content that contains the word “shit” and all of its variants, unless used in the form of a personal attack, e.g., “You don’t know shit.”
- “Ass”, “Crap”, “Bullcrap”, “Hell”, & “Damn”
  - Permit these words and their variants - kick ass, bad ass, pain in the ass, etc., unless used in the form of a personal attack, e.g., "I'm going to kick YOUR ass."
- Pornographic content & Sexually graphic or explicit language
  - Remove all pornographic content as well as sexually graphic or explicit language. Apply the standard of PG-13 TV. For example, it is ok for fans to say, "WW has helped me look sexier than ever!" However, it is not ok for fans to describe sexual acts in detail.
- Camouflaged spellings, e.g., “f*ck” or “p0rn”
  - Moderate words with transparently camouflaged spellings as you would their obvious stand-ins, e.g., “f*ck” is permitted, as long as it is NOT used as a personal attack.
- Acronyms
  - Permit acronyms with widespread cultural acceptance, e.g., "WTF" or "LMFAO".

Personal Attacks

- Remove all content that includes personal attacks. This includes disrespecting, insulting, or attacking users or posts in an aggressive manner. For example:
  - Calling other users losers, idiots, morons, etc., are all considered personal attacks.
  - Lewd, suggesting, crude, or cruel comments directed toward other users should also be removed.

- This can refer to either a specific individual or a group of people (e.g. “You idiots on this thread need to shut up”)
- Permit friendly banter using your own discretion.
- Remove all content that may result in others feeling threatened, specifically targeted, or abused.
- Remove all content inciting or directly referring to violence, past violence, or the threat of violence.

Trolling

- A troll is "someone who posts inflammatory, extraneous, or off-topic messages with the primary intent of provoking readers into an emotional response or disrupting normal on-topic discussion."
- Individual trolling posts may not violate any one particular guideline.
- It will be up to the Senior Resolution Specialist to identify trolling attempts and take appropriate action (removal, banning).

Discrimination, Religious, and Political Themes

- Remove all content that advocates or condones discrimination or prejudice based upon race, color, religion, creed, sex, sexual orientation, national origin, age, disability, or veteran status.
- Remove all content that advocates religion or religious themes or imagery. An author mentioning religion would not typically be offensive to others and is acceptable. However, an author advocating or pushing religion, or criticizing another's lack of, is NOT acceptable.
- Remove all content that provokes and calls on a specific action in response to a political and/or current event. If the content clearly states how these political issues relate to their wellness journey, do not remove/hide post. All political posts should be downtrended.

Benefits: [Describe anticipated benefits to the individual participants. If test results will be provided, describe and explain procedures to help participants understand the results. If individual participants may not benefit directly, state so here. Do not include compensation or earned course credits in this section.]

Participants may or may not benefit from participating in the study. Benefits that could occur are losing weight through the exercise and lifestyle changes. Through interacting with other participants and the coach during the virtual workshops, participants may also feel supported in their behavioral change efforts.

[Describe anticipated benefits to society (i.e., added knowledge to the field of study) or a specific class of individuals (i.e., athletes or autistic children).]

Societal benefits include providing evidence to support intervention delivery modalities that are more conducive to modern lifestyle (i.e., more virtual options).

Risk/Benefit Analysis: [Describe the ratio of risks to benefits. Risks to research participants should be justified by the anticipated benefits to the participants or society. Provide your assessment of anticipated risks to participants and steps taken to minimize these risks, balanced against anticipated benefits to the individual or to society.]

The possible risks of the study (including injury during exercise, psychological discomfort while completing surveys or using the WW app, and breach of confidentiality) are minimal and are outweighed by the possible benefits to participants (weight loss).

Economic Considerations: [Describe any costs to the participants or amount and method of compensation provided. Describe how you arrived at the amount and the plan for compensation; if it will be prorated, please provide the breakdown. Experimental or extra course credit should be considered an economic consideration and included in this section. Indicate when participants will receive compensation.]

Economic burden to subjects includes the time needed for screening and study participation. There is no cost to participants for participating in the study. Depending on smartphone data usage plan for each participant, usage charges may incur due to increased use of mobile apps.

Participants will be paid in the form of online Amazon gift cards. Participants will receive $20 compensation for completing the baseline visit, $50 for completing the 3-month survey, and $50 for completing the 6-month survey. Additionally participants will be allowed to keep the study scale.

Participants who complete the Qualtrics initial screening survey, whether or not they participate in this study, will receive Qualtrics incentives. Their incentives are based on a points system. Respondents accumulate points as they take surveys and then trade in points for E-gift cards to anywhere of their choice (amazon, walmart, target, etc.). The compensation Qualtrics provides is separate from the compensation for participating in the baseline and follow-ups of this trial.

Data Safety Monitoring: [This is a prospective plan set up by the study investigators to assure that adverse events occurring during studies are identified, evaluated, and communicated to the IRB in a timely manner. Although the investigators initially propose a Data Safety Monitoring Plan (DSMP), the IRB must approve the plan and may require revision of the plan. A DSMP is required for all human studies at the University of Connecticut except for studies reviewed under the Exempt Criteria. For studies that present more than minimal risk to participants, the IRB will review and determine on a case-by-case basis whether a data safety monitoring board is most appropriate. Please refer to the IRB's policy regarding data safety monitoring *before* completing this section - http://research.uconn.edu/policies-procedures.

Issues that should be addressed in the DSMP include the following:

1. Frequency of the monitoring.
2. Who will conduct the monitoring (Under UConn policy a student cannot be the sole person responsible for monitoring the data and safety of the protocol procedures?)
3. What data will be monitored (include compliance with approved IRB protocol?
4. How the data will be evaluated for problems?
5. What actions will be taken upon the occurrence of specific events or end points?
6. Who will communicate to the IRB and how will communication will occur?
7. Describe procedures to inform the sponsor.

Sample response to issues listed above for minimal risk/slight increase over minimal risk – "Survey results will be monitored by the PI in conjunction with the student investigator once every two weeks (items 1, 2 and 3). Survey responses will be reviewed to monitor for clarity (i.e., the same question is

skipped by 5 or more participants). In that case, the question will be revised and an amendment will be submitted to the IRB (items 4, 5 and 6)."

Since this study is minimal risk we will not have a safety board. Data will be monitored by the data manager weekly and at the end of each assessment phase. Data from tracking forms and surveys, and engagement data received from WW will be cleaned and assessed for missingness. A full report will be generated at 6-months for PI and WW review. The report will be submitted to the IRB at the closing of the project.

Adverse events will be assessed at follow-ups UConn staff will follow an AE protocol, which will include instructions on what is considered an adverse event and what steps are needed to be taken.

Privacy/Confidentiality Part 1: [Explain how the privacy interests of participants will be maintained during the study (note that **privacy pertains to the individual not to the data**). Describe how data will be coded. Do not use the any potentially identifiable information such as initials of participants as part of the code. Explain how long data will be kept in an identifiable format and how long de-identified data will be retained. Explain how long the master key or audio or video recordings obtained, will be kept. Consider whether keeping de-identified data will be retained indefinitely and whether participants may be contacted for a follow-up study (explain procedures to retain identifiable contact data is kept.]

REDCap will be used for data entry and management. The database will be maintained on UConn servers where security will be maintained through access controls. Files will be managed by the data manager and project coordinators, who will control user access and rights. For each user, REDCap will require a REDCap profile, username and password to enter the program. Staff will only have access to the database if the data manager has given them access. UConn IRB and their representatives, and study personnel will have access to the research data, as will the study sponsor if requested. All participants will be assigned an ID number, which will link them to their study data. The ID number will be 3-4 numerical characters representing the number of participants in the study. PHI fields will be stored in a separate REDCap form from other data collection forms. Data will be completely de-identified once the last assessment is complete and cleaned the data and assess for any missingness or errors. At this time the link between ID number and study data will be destroyed. Study data in the form of hard copies will be stored in a locked file cabinet managed by the program director and will be destroyed 5 years after completion of the study.

WW scales will be used to collect weight from participants. The scale will be mailed directly from WW to the participant.

Participant information entered into the WW app and any data from the virtual workshops will be transmitted from the WW investigator to the Research Coordinators Kaylei Arcangel and Joseph DiVito using a UConn OneDrive folder that only Kaylei and Joe (and WW) will be given access to. Records will contain the WW membership ID number, which UConn can use to link to study ID. Only UConn will hold the master key to the assessment data and study ID numbers. Only data relevant to participants in this study will be given to UConn investigators.

If identifiable, sensitive information (illegal drug use, criminal activity, etc.) will be collected, state whether a Certificate of Confidentiality will be obtained.

N/A

Be sure to state whether any limits to confidentiality exist (e.g. mandated reporting) and identify any external agencies (study sponsor, FDA, etc.) that will have access to the data.

WW will see participant use data that is entered into the WW appVirtual Workshops and in the Facebook group. WW will also have participant contact information from the NDA (name, email, phone, and address) and the technical troubleshooting email communication. WW may also email participants materials pertaining to weekly topics in the Virtual Workshops or regarding the food plan. Participants sign up for the app using their email address. This is no different from the commercially available app or commercially available plans WW offers. Additionally, we will send them de-identified assessment data as well as project reports. There is a chance that they will be able to link the assessment data with the engagement data entered into WW app virtual workshops and the Facebook group through participants comments and weight entries. Additionally, it is possible that participants in this study know each other.

If participants will be screened, describe the plans for storage or destruction of identifiable data for those that failed the screening.]

Contact information will be stored in a REDCap form with an indication that they are not eligible. However the data collected from the screening, including reason ineligible, will be stored in a separate form and will be de-identified at the end of the study.

Privacy/Confidentiality Part 2: Complete the Data Security Assessment Form

: [**This form IS REQUIRED for ALL studies**. The form is available here - https://ovpr.uconn.edu/services/rics/irb/irb-forms-infoed/. This form will be used to assess procedures for protecting confidentiality of data collected during the study and stored after closure. It will also be used to assess plans for storage and security of electronic data in accordance with University Best Practices. Review the document proving tips to complete the form located at http://content.research.uconn.edu/pdf/storrs/rcs/irb/TipsDataSecurityAssessmentForm.docx.

Informed Consent

As PI, you are responsible for taking reasonable steps to assure that the participants in this study are fully informed about and understand the study. Even if you are not targeting participants from "Special Populations" as listed on page 4, such populations may be included in recruitment efforts. Please keep this in mind as you design the Consent Process and provide the information requested in this section.

Consent/permission Setting: [Describe the consent/permission process including *who* will obtain it, *where* and *when* will it be obtained, and *how* much time participants will have to make a decision. Describe how the privacy of the participants will be maintained throughout the consent process.

A signed consent waiver is being requested for this study. Participants will review an informational page before completing the initial survey screener. Ample time will be allowed for

discussion or questions. Consent will be reviewed during the telephone screening by research assistants/coordinators trained in the consent process.

State whether an assessment of consent/permission materials will be conducted to assure that participants understand the information (may be warranted in studies with complicated study procedures, those that require extensive time commitments or those that expose participants to greater than minimal risk).]

We will not perform an assessment to ensure participants understand the information, however we will conduct an interactive webinar to discuss any concerns or questions.

Capacity to Consent: [Describe how the capacity to consent will be assessed for participants with limited decision-making capacity, language barriers or hearing difficulty. If a participant is incapable of providing consent, you will need to obtain consent from the participant's legal guardian (please see the IRB website for additional information).]

To be able to actively participate in the study, participants must be adults without impaired decision making ability that are able to speak and read English. The consent process will include a discussion of the participants understanding of what participating in research means including their rights as a research participant, the protocol, as well as risks and potential benefits to participating in the study. If research personnel obtaining consent believes there is a concern regarding a participant understanding participation will be discussed with the program director who will determine whether to exclude the participants on this basis.

Parent/Guardian Permission and Assent: [If enrolling children, state how many parents/guardians will provide permission, when the child's assent will be obtained and if assent will be written or oral. Provide a copy of the script to be used if oral assent will be obtained. For longitudinal studies, assent may happen at several points during the study.]

N/A

Documentation of Consent: [Specify the forms that will be used for each participant population, i.e., adult consent form, surrogate consent form, parental permission sheet. child assent form (written form or oral script) or an information sheet. Copies of all forms should be attached to this application in the same format that they will be given to participants (templates and instructions are available on the IRB website).]

An information sheet will be used for the study participants.

Waiver or Alteration of Consent: [The IRB may waive or alter the elements of consent in some minimal risks studies. If you plan to request either a **waiver of consent** (i.e., participants will not be asked to give consent), an **alteration of consent** (e.g., deception) or a **waiver of signed consent** (i.e., participants will give consent after reading an information sheet), please answer the following questions using specific information from the study:]

Waiver (i.e. participants will not be asked to give consent) or alteration of consent (e.g. use of deception/incomplete disclosure in research):

- Why is the study considered to be minimal risk?

- How will the waiver affect the participants' rights and welfare? The IRB must find that participants' rights are not adversely affected. For example, participants may choose not to answer any questions they do not want to answer and they may stop their participation in the research at any time.
- Explain why the research could not be practicably carried out without the waiver. For studies that involve deception, explain how the research could not be done if participants know the full purpose of the study.
- Explain why the research could not be practicably carried out without using identifiable private information and/or identifiable biospecimens.
- How will important information be returned to the participants, if appropriate? For studies that involve deception, indicate that participants will be debriefed and that the researchers will be available in case participants have questions.
- Indicate if the waiver/alteration as noted above is applicable to the entire study or to a portion of the study.

Waiver of ***signed*** consent (i.e. , no signature, participants give consent only after reading an information sheet). Tip: if the investigator will obtain information through oral or written communication with the prospective participant or if the investigator will obtain private identifiable information or identifiable biospecimens by accessing records, then a waiver of signed consent is NOT required.,:

We are requesting a waiver of signed consent to be able to recruit participants across the US for an online study.

- Why is the study considered to be minimal risk?

  The study is minimal risk because includes surveys and a weight loss intervention. The weight loss intervention is commercially available.

- Does a breach of confidentiality constitute the principal risk to participants? Relate this to the risks associated with a breach of confidentiality and indicate how risks will be minimized because of the waiver of signed consent.

  The ability to review the consent online will limit any risks of travelling to the study site needed to complete an in-person consent.

- Would the signed consent form be the only record linking the participant to the research? Relate this to the procedures to protect privacy/confidentiality.

  No. We also utilize contact information to communicate with participants throughout the study.

- Does the research include any activities that would require signed consent in a non-research setting? For example, in non-research settings, normally there is no requirement for written consent for completion of questionnaires.

  No.

- Describe if the participants or their legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects and there is an appropriate alternative

mechanism for documenting that informed consent was obtained. Not applicable to FDA Regulated Studies.
N/A

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