Study to Evaluate the Efficacy of a Multimodal Digital Behavior Change Intervention on Lifestyle Behavior, Cardiometabolic Biomarkers, and Medical Expenditure: Protocol of a Randomized Controlled Trial

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Table of Contents

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Abstract

Background: The US Preventive Services Task Force recommends providers offer individualized healthy behavior interventions for all adults, independent of their risk of cardiovascular disease. While strong evidence exists to support disease-specific programs designed to improve multiple lifestyle behaviors, approaches to adapt these interventions for a broader population are not well-established. Digital Behavior Change Interventions (DBCI) hold promise as a more generalizable and scalable approach to overcome resource and time limitations that traditional behavioral interventions programs face, especially within an occupational setting.

Objective: We aimed to evaluate the efficacy of a multimodal DBCI on 1) self-reported behaviors of physical activity, nutrition, sleep, and mindfulness, 2) cardiometabolic biomarkers, and 3) chronic disease-related medical expenditure.

Methods: We conducted a two-arm randomized controlled trial for 12-months among employees of an academic healthcare facility in the US. The intervention arm received a scale, smartphone app, activity tracker, video library for healthy behavior recommendations, and an on-demand health coach. The control arm received standard employer-provided health and wellness benefits. Primary outcomes of the study included changes in self-reported lifestyle behaviors, cardiometabolic biomarkers, and chronic disease-related medical expenditure. We collected health behavior data via baseline and quarterly online-surveys, biometric measures via clinic visits at baseline and 12 months, and identified relevant costs through claims datasets.

Results: A total of 603 participants were enrolled and randomized to the intervention (n = 300) and control arms (n = 303). The average age was 46.7 years, and participants were majority female (80.3%), White (85.4%) and non-Hispanic (90.7%), with no systematic differences in baseline characteristics observed between the study arms. We observed retention rates of 83.7% for completing the final survey and 75.7% for attending the exit visit.

Conclusions: This study represents the largest and most comprehensive evaluation of DBCI among participants who were not selected based on their underlying condition to assess impact on behavior, cardiometabolic biomarkers, and medical expenditure.

Trial Registration: Clinical Trials Registry (#NCT04712383), Date: January 13, 2021 https://clinicaltrials.gov/ct2/show/NCT04712383

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Keywords: Health Behavior, Fitness, Digital devices, Lifestyle change

Introduction

In July 2022, the United States Preventive Services Task Force (USPSTF) recommended that providers offer personalized health behavior interventions for improving diet and physical activity to all adults in the United States (U.S.), independent of an individual's underlying risk for cardiovascular disease.[1] Tacit within this recommendation is a recognition that Americans, generally speaking, have suboptimal lifestyle behaviors [2, 3] and have an increased risk of

cardiovascular disease. Less than half of all Americans engage in the recommended 150 minutes per week of moderate intensity aerobic activity or 75 minutes/week of vigorous physical activity, and only 12.3% and 10% of surveyed adults in the United States meet the recommended daily intake of fruit or vegetables, respectively [4, 5]. It is estimated that half of all American adults (117 million individuals) have at least one or more chronic diseases [4, 6] and cardiovascular disease is the number one cause of death and disability [7, 8]. Evidence suggests that chronic disease incidence and progression is accelerated by suboptimal health behaviors [9–12]; conversely, improving lifestyle behavior can prevent onset of chronic disease or modify its trajectory [13–18].

Strong evidence for the ability of an intervention to improve multiple lifestyle behaviors and prevent or delay disease onset comes from the literature surrounding the Diabetes Prevention Program, which focuses interventions among the pre-diabetic population and has demonstrated as much as 30-60% reduction in incidence of diabetes [19]. [20, 21]Additionally, scaling up the Diabetes Prevention Program required significant support from the Centers for Disease Control including increasing workforce expansion to implement the program cost-effectively, standardizing program implementation to assure quality, providing infrastructure resources to build sites that can provide the program, and developing a network to increase referrals for use of the prevention program [20, 21]. . However, translation of these effects for a more generalized population is not well-established [20, 21]. Certainly, extending this model to all adults, independent of their risk of chronic disease, would require a huge financial and logistical undertaking, which, may not be feasible.

Digital behavior change interventions (DBCI) use mobile apps, wearables, computer programs, or websites to prevent disease through health behavior promotion and hold promise to overcome resource and time limitations that traditional behavioral interventions programs face [22–24]. Indeed, digitization of the Diabetes Prevention Program has demonstrated similar treatment effects [25–27]. Efforts to evaluate feasibility of implementation and maintenance of in-person and

digital Diabetes Prevention Program are underway and will provide critical insight for scaling up implementation of digital approaches [28, 29]. Whether the success of a digital Diabetes Prevention Program translates to the general population, i.e., with and without pre-diabetes, remains unknown. Thus, rigorous evaluation of a holistic DBCI in the general population is needed in light of the U.S. Preventive Services Task Force's recommendation. However, investigating the effects of multimodal intervention on a diverse set of behaviors is difficult and recruitment, retention, and DBCI adherence pose a challenge for conducting these types of studies in populations that are not recruited from clinics or on the basis of their underlying conditions.

Occupational settings provide a unique opportunity to engage a large proportion of the adult population in lifestyle behavior intervention and has been endorsed by the American Heart Association [30]. In addition to promoting healthy behavior among adults, wellness programs through the workplace can boost morale and improve productivity [31, 32]. Additionally, DBCI programs are less likely to be disruptive in an occupational setting in comparison to traditional programs, and therefore, more likely to experience higher engagement and adherence. However, availability of resources such as in-person coaching, room and space availability, time-off from work responsibilities, constrain the ability to scale behavioral interventions.

To address these issues,, we present a framework for DBCI that integrates the health-belief model with proposed mechanisms of lifestyle interventions' effect on chronic conditions as a precursor to subsequent research that will describe the primary outcomes of our innovative study. In this manuscript, we describe the design of the UMass Fitbit Care Study, which evaluates a multimodal DBCI provided by Fitbit among healthcare employees in Central Massachusetts. The primary objectives of the UMass Fitbit Care Study were to evaluate the efficacy of intervention on:

1. Change in self-reported lifestyle behaviors on physical activity, nutrition, sleep, and mindfulness among participants,
2. Cardiometabolic biomarkers over a 12-month period, and

3. Chronic disease related medical expenditure.

Our hypothesis is that self-reported lifestyle behaviors are going to be a proximal outcome affected by the intervention and likely to show strongest treatment effect, cardiometabolic biomarkers will be more distal and show a modest treatment effect, and medical expenditure will be the most distal outcome and demonstrate a minimal treatment effect during the study period, but may reveal a trend towards reduced expenditure among the intervention group.

Secondary objectives of the UMass Fitbit Care Study were to characterize:

1. Trajectories of intervention engagement over a 12-month period,
2. Differential engagement of the Fitbit Intervention in relation to baseline behavior and comorbidities, and
3. Differential efficacy of intervention based on engagement.

Methods

Study design

The UMass Fitbit Care Study is a dual-arm, open-label randomized clinical trial with a 12-month study period. SPIRIT reporting guidelines were used in the development of this protocol and fulfilled the SPIRIT checklist [33]. Participants were randomized to intervention or control arm using a permuted block randomization that stratified based on age (<= 40, 40+) and sex to achieve a balance for those two demographic variables between the intervention and control group (Figure 1). Participants were randomized 1:1 to an intervention-arm, where participants received their standard health and wellness benefits as provided by their employer, plus a digital behavioral change intervention through Fitbit or control-arm, where participants only received their standard health and wellness benefits during the study period. The Fitbit DBCI included five components: a wearable

health and fitness device (participant choice of Fitbit Inspire 2 tracker or Versa 3 smartwatch), a wireless weight scale (Fitbit Aria Air), the Fitbit app (provided basic tracking and goal setting functionalities), Fitbit Premium (provided additional advanced metrics and rich video content through the Fitbit app), and an on-demand human health coach (provided goal setting, action planning, and accountability support through the secure, asynchronous, in-app messaging).

Study Setting and Participants

This study was conducted in Worcester, Massachusetts, with employees of UMass Memorial Health (UMMH). To be eligible, participants must have been enrolled on a UMMH-sponsored health plan, had to own a smartphone, had to be 18 years or older, and agreed to consent to the study (Figure 1). Participants who were pregnant at the time of enrollment, did not speak English, or were incarcerated, were excluded from the study. The study had an a-priori enrollment goal of up to 700 employees, which represents roughly 7.5% of all eligible population. The sample size for this study was derived based on pragmatics of resource availability. All eligible employees were invited to participate in the study through electronic communication and a home mailer. To be enrolled in the study, participants had to electronically sign an informed consent, fill out a baseline survey and demographics, use a self-scheduling service to pick an appointment for their initial biometric screening, and then complete said screening, in-person. Participants were then randomized to either the intervention or control arm. A permuted block design with random block sizes was used to generate the randomization sequence. That sequence was loaded into a REDCap randomization module so that it was readily available during the in-person screening process. Participants were asked to schedule an exit biometric screening at the end of the 12-month study period. Because, this intervention being investigated is designed to help users improve their health behaviors in alignment with the advice of their healthcare providers and not to make medical decisions, the risk of harm to health is low. Participants were free to withdraw from the study at any time.

Ethical Considerations

A trial steering committee consisting of two principal investigators JM and SB met bi-weekly to provide supervision of the study, ensure progress milestones were met, and communicate important protocol updates to relevant parties. The study was reviewed and approved by the University of Massachusetts Chan Medical School Institutional Review Board (Approval number #H00021669) and registered on Clinical Trials registry (#NCT04712383) on January 13, 2021. All participants had to electronically sign an informed consent to participate in the study. Entrance and exit biometric exam data was collected and held by Quest Diagnostics and electronically transferred to the University of Massachusetts Chan Medical School (UMass Chan) where it was stored on an encrypted server approved for data containing personal health information (PHI) and personal identifying information (PII). The medical claims data from Conifer were also transferred to the same server for analysis. Participants who completed both the entrance and exit biometric screenings were provided a $100 incentive via a Visa e-gift card. Additionally, participants assigned to the intervention arm were able to keep the Fitbit wearable device and weight scale received during the study and those assigned to the control arm received a Fitbit wearable device at their exit screening appointment.

Fitbit DBCI Components

Wearable Health and Fitness Device

Intervention participants had a choice of a Fitbit Inspire 2 tracker or a Fitbit Versa 3 smartwatch. Both devices provided comparable health and fitness tracking features capabilities including steps, distance, energy burn, exercise, heart rate, Active Zone Minutes (measure of moderate-to-vigorous physical activity based on Physical Activity Guidelines for Americans), and sleep. The Inspire 2 had a smaller, bracelet-like form factor and longer battery life (~10 days) while the Versa 3 had a watch form factor, additional smartwatch features (built-in GPS, apps, etc.), and a shorter battery life (~6 days).

Wireless Scale

The Fitbit Aria Air scale provided intervention participants with a simple wireless (Bluetooth) scale that integrated with the Fitbit app for ease of weight trend tracking.

Fitbit App

The Fitbit app provided intervention participants with features to enhance tracking and goal setting for each of the health and fitness measures tracked by their wearable device. For example, the Active Zone Minutes (AZM) feature in the app allowed users to see graphs of their trends in moderate-to-vigorous physical activity over time (daily, weekly, monthly, etc.) and to set personal goals for the number of AZMs to achieve in a day and a week. As another example, the sleep tracking feature allowed them to see their sleep duration, bedtime and wake up time consistency, and time spent in different sleep stages and to see trends in these measures over time as well as set goals for sleep duration, bedtime, and wake up time.

Fitbit Premium

Participants assigned to the intervention arm also received Fitbit Premium. Fitbit Premium is a subscription membership service that provides advanced scores and rich content within the Fitbit app to enhance participant experience. The advanced scores, included in both Sleep Score and Stress Management Score, provide additional feedback and insights to users on these dimensions of their wellness. The rich content includes hundreds of workout videos and mindfulness audio sessions as well as healthy recipes, all designed to help users improve their health behaviors. (Figure 3)

On-Demand Human Health Coach

Each intervention participant was paired with a personal, human health coach that provided goal setting, action planning, and accountability support for health behavior improvement across activity, nutrition, sleep, and mindfulness with emphasis on the domain(s) desired by the participant at any moment in time. The health coaches sent a secure, asynchronous, in-app text message within a day of enrollment to each participant to start the process of creating a goal(s) and an action plan for

improving the behavior(s) when the participant's motivation and confidence was greatest. For example, there might be an exchange of a few messages to determine that a particular user wanted to focus on improving sleep. The coach might help that user set a goal about a regular sleep schedule and an action plan for doing a mindfulness session before bed and not bringing electronic devices to bed. (Figure 4)

The health coach then sent a message every day or every other day for the first few weeks to encourage the participant to stick with the plan and to provide support for follow-through or adjustment of the plan. The health coaches monitored core Fitbit data from the users (steps, AZMs, sleep, etc.) via a dashboard to help tailor their support. The frequency of messages decreased as the participant gained self-efficacy; however, the option to increase messaging remained if the participant wanted extra support. Each participant was free to use any of the software features of the Fitbit app and Fitbit Premium as desired throughout the course of the intervention, although the health coach made recommendations on features, workout videos, mindfulness sessions, etc. that might be most helpful based on the participant's goals, action plan, and device data. If participants were unresponsive for several weeks or requested to discontinue coaching, the health coaches archived their profiles in their dashboard and ceased sending them messages unless the participant proactively re-engaged by sending the coach a message.

Data Collection and Management

There were four forms of data collected: 1) survey data through baseline survey and scheduled quarterly surveys for all participants, 2) Fitbit-tracked data for those participants assigned to the intervention arm, 3) biometric data for all participants, which include anthropometric and vital sign measurements and laboratory investigations performed by Quest Diagnostics, LCC (Marlborough, MA), and 4) total medical expenditure claims data abstracted by Conifer Health Solutions for all participants. (Figure 5) describes all data collected as part of this study. An initial invitation to participate in the study was sent via email to a list of pre-determined eligible employees.

Interested participants signed up for the study by entering their email address, signing the consent and filling out their baseline survey and demographics, and presented at an in-person biometric screening appointment performed by Quest Diagnostics staff. At this first visit for the biometric screening, participants were randomized and scheduled for the four follow-up quarterly surveys. All survey data collection was performed using the REDCap data collection platform. SAS (SAS Institute, Cary, NC) was used for all analysis. The final trial dataset which consists of survey questionnaire data, Fitbit device data, Quest biometric data, and Conifer claims data is only available to partners within the UMass Chan Department of Population and Quantitative Health Sciences who were responsible for the analysis.

Statistical Analysis

We present descriptive statistics for baseline characteristics and overall engagement among the participants assigned to the intervention group in this manuscript using proportions and mean for the distribution of categorical and continuous variables, respectively. The study will evaluate its primary objectives using intention-to-treat analysis. A 2-tailed student’s t-test for independent samples will be used to compare the mean of continuous variables and chi-square or Fisher's exact test will be used to compare categorical variables between the intervention and control group. Secondary objectives will be evaluated using group-based trajectory modeling to identify distinct trajectories of engagement and adherence, association of distinct trajectories with baseline behavior and comorbidities, and performing an intervention-only analysis where treatment effect of the intervention is evaluated across different trajectories of engagement. Additional exploratory analyses will consider accounting for possible contamination based on self-reported use of wearable health and fitness devices among the control group participants. There are no plans to use biological specimens in ancillary studies. Data collection questionnaires can be provided upon request.

Results

Baseline characteristics

A total of 13,391 employees were eligible to enroll in the UMass Fitbit Care Study and received an email or home mailer about participating in the study. Of those invited, 758 completed consent to participate in less than 24 hours, and scheduled an appointment for initial biometric screening. The follow-up rate was 75.7% with 603 individuals attending the biometric screening and getting randomized to intervention (n = 300) or control group (n = 303). Baseline characteristics of these two groups are provided in Table 1 and no systematic differences were observed between the two groups. On average, participants were 46.7 years of age (SD: 11.2), majority of the participants were female (80.3%), white (85.4%), and non-Hispanic (90.7%). More than half of the participants had baseline BMI that classified them as overweight or obese (74.8%).

Intervention engagement and participant retention

To approximate real-world scenarios, this study did not have a specific plan to promote participant engagement with the intervention or retention of participants in the study beyond ensuring their Fitbit device was synced with the mobile application and initial communication with their personal health coach occurred. The median wear time for Fitbit was observed to be 325 days (IQR: 154-372) and 264 participants (88.0%) used health coaching at least once. Of the 603 participants that completed entrance screening and thus were included in the study, 8 withdrew, 519 (intervention = 251; control = 268) completed exit surveys and 469 (intervention = 227; control = 243) completed exit biometric screening (Figure 2).

Discussion

We describe the design, rationale, and baseline characteristics from a randomized control trial of a multimodal DBCI from Fitbit on improving lifestyle behaviors and cardiometabolic health in a general, rather than disease-specific, population. The high retention rate and balanced distribution of baseline characteristics paired with a comprehensive assessment of the intervention’s impact on

behavioral, cardiometabolic biomarkers, and medical expenditure, will allow for detailed evaluation of the intervention for primary and secondary endpoints.

Research on the effectiveness of DBCIs for chronic disease prevention has yielded mixed results with regard to behavioral change and cardiometabolic outcomes. One randomized controlled trial led Toro-Ramos et al. assessed the effectiveness of a lifestyle app in prediabetic individuals in which significant weight loss was observed in the intervention group but there was no significant difference in HbA1c levels between the intervention and control groups at one year (mean difference 0.006%; *P*=.93) [34, 35]. Likewise, another study investigating a mobile diabetes prevention program found a 1.9% decrease in HgBA1c among intervention participants compared to the control group, but there were no improvements in patient-reported behaviors such as mood after 12 months [36]. Additionally, such interventions have often focused on evaluating behaviors within disease-specific populations [34, 37–40].

Therefore, we aim to adopt a more holistic approach to behavior change intervention research by evaluating the effectiveness of a DBCI intervention in a broader, real-world population and assessing changes in behavior across four key areas: physical activity, nutrition, sleep, and mindfulness. Additionally, we will conduct comprehensive biometric evaluations using both digital and laboratory biomarkers, which will contribute valuable insights to the existing literature.

There are several potential mechanisms through which Fitbit DBCI can affect healthy behavior changes, which lie upstream of factors that impact onset and progression of chronic diseases. The Lifestyle Medicine Research Summit proposed that promotion of healthy lifestyle behavior can interrupt the pathogenesis of chronic diseases and possibly reverse it [41–44]; the Health Belief Model is a well-established theory to explain an individual's decision-making for a behavioral change [45]. We propose that an integration of these two frameworks, as described in (Figure 6), can provide theoretical underpinning for the impact of the Fitbit DBCI on chronic diseases. Fitbit DBCI's ability to pair tracking of behavior with nudges and coaching that can be

delivered through telecommunications and motivational messaging can act on lifestyle behaviors which lie upstream of factors that lead to chronic diseases [37, 46–50]. Support for individual goal setting and self-monitoring through alerts based on certain patterns of inactivity or pushing motivational messages based on accomplishment of healthy behaviors can motivate individuals, promote self-efficacy, and provide cues for action [51–53]. It offers a holistic approach for improving lifestyle behaviors and is responsive to the US Preventive Services Task Force recommendation for tailoring behavioral intervention to individual's needs.

In our study, we observed a high adherence of wearable devices, with a median wear time of 325 days. We had an 84% retention rate for exit surveys that evaluated self-reported behavioral outcomes and a 76% retention rate for exit visits that measured cardiometabolic biomarkers. Our results are consistent with findings from prior research on DBCIs for diabetes and hypertension prevention [26, 39].

Further secondary analysis of the data from this study can inform the feasibility and acceptance of providing multimodal DBCI for employees in a workplace setting. Additionally, through collection of data over the course of the year from the Fitbit intervention, we will be able to perform secondary data analysis that characterizes the intensity of coaching intervention, which is likely to be a key determinant of its efficacy. A three-year study showed that individualized biweekly counseling decreased sedentary time and promoted healthy behavior [41, 42]. However, it is unlikely that all users of the program require an intervention of this intensity. We will be able to perform analysis to understand factors associated with goal setting and self-efficacy of participants for affecting behavioral change as measured through standardized questionnaires. Thus, our findings will inform optimal intervention practices for implementing DBCI programs at-scale where participant reported outcomes can be used to facilitate tailored behavioral counseling to participants and align DBCI programs with US Preventive Services Task Force recommendations of individualizing interventions.

Strengths and Limitations

Several aspects of the study represent methodological strengths which include the use of a randomized design, rigorous and standardized outcome evaluation, and robust adherence to the protocol. However, the study's limitations should also be noted when interpreting results from this study. Our study lacks an active control and therefore we cannot estimate treatment effects of activity tracking and DBCI separately. However, the intended use of Fitbit health coaching is as a combination and therefore this study estimates the combined treatment effect of this multimodal intervention. Our study sample underrepresents Black/African American, Hispanic, and Asian staff, suggesting a need for future studies to implement robust recruitment strategies to target underrepresented groups. Moreover, our study sample was selected from employees at an urban academic medical center, which may suggest that these participants are already engaging in healthy behaviors given their health backgrounds. Our study sample included individuals who volunteered to participate in digital health research. Our baseline characteristics suggest that there is skewness in demographic representation such that individuals more likely to participate in these studies are enrolled in this study, which may account for our high adherence and retention rates. While that limits the generalizability of the study findings, the randomized assignment of intervention balances possible bias that may emerge from early responders to the invitation. Lifestyle behavior was measured using standardized surveys with high face validity, but these were not validated instruments, e.g. Pittsburgh Sleep Quality Index, 24-hour food recall, perceived stress scale, etc., which limits external generalizability of the findings, however differences between groups in these measures are unlikely to be affected by it.

Conclusions

To our knowledge, this is one of the largest evaluations of a multimodal Digital Behavior Change Intervention (DCBI) impact on physical activity, nutrition, sleep, and mindfulness among participants who were recruited independent of their underlying disease status. It is also among one

of the only studies that comprehensively evaluates the impact of the DBCI on the sequelae of healthy behavior by measuring cardiometabolic biomarkers and abstracting medical expenditure data. Finally, data from this study can help understand adherence to DBCI over the period of one year and elucidate the association between intensity of coaching, self-reported motivation for changing behavior, and objective measurement of health behavior trajectories from wearable health and fitness devices and wirelessly connected scale. Taken together, findings from this study have the promise to provide useful insights for individualizing the Fitbit intervention among otherwise healthy people as recommended by the 2022 US Preventive Services Task Force.

Tables and Figures

Figure 1. UMass Fitbit Care Study Design: Health behavior data was collected through baseline and quarterly online surveys, while biometric measurements were obtained during clinic visits at baseline and at the 12-month follow-up. The exit screening phase concluded in January 2022.

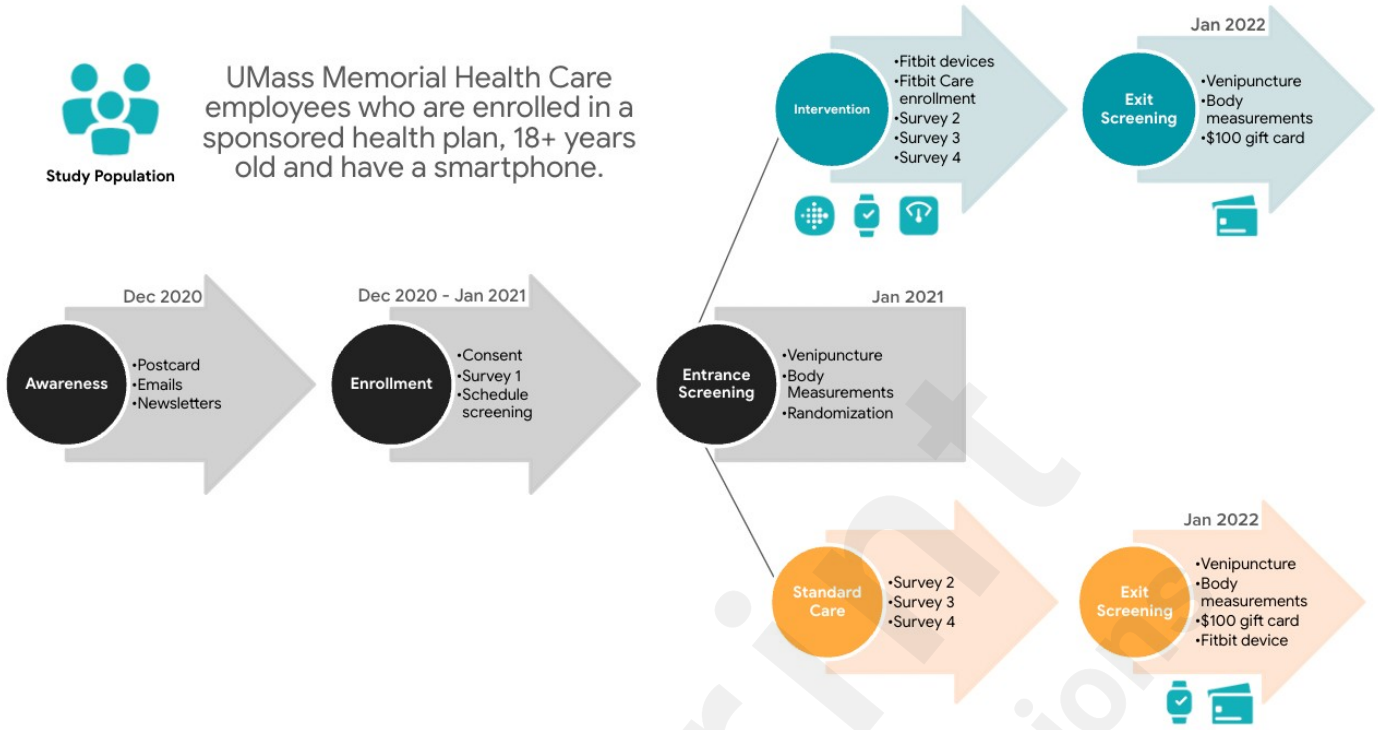

Figure 2. UMass Fitbit Care Study Participant Flow: Flow of participants through UMass Fitbit Care Study, showcased by the CONSORT (Consolidated Standards of Reporting Trials) diagram.

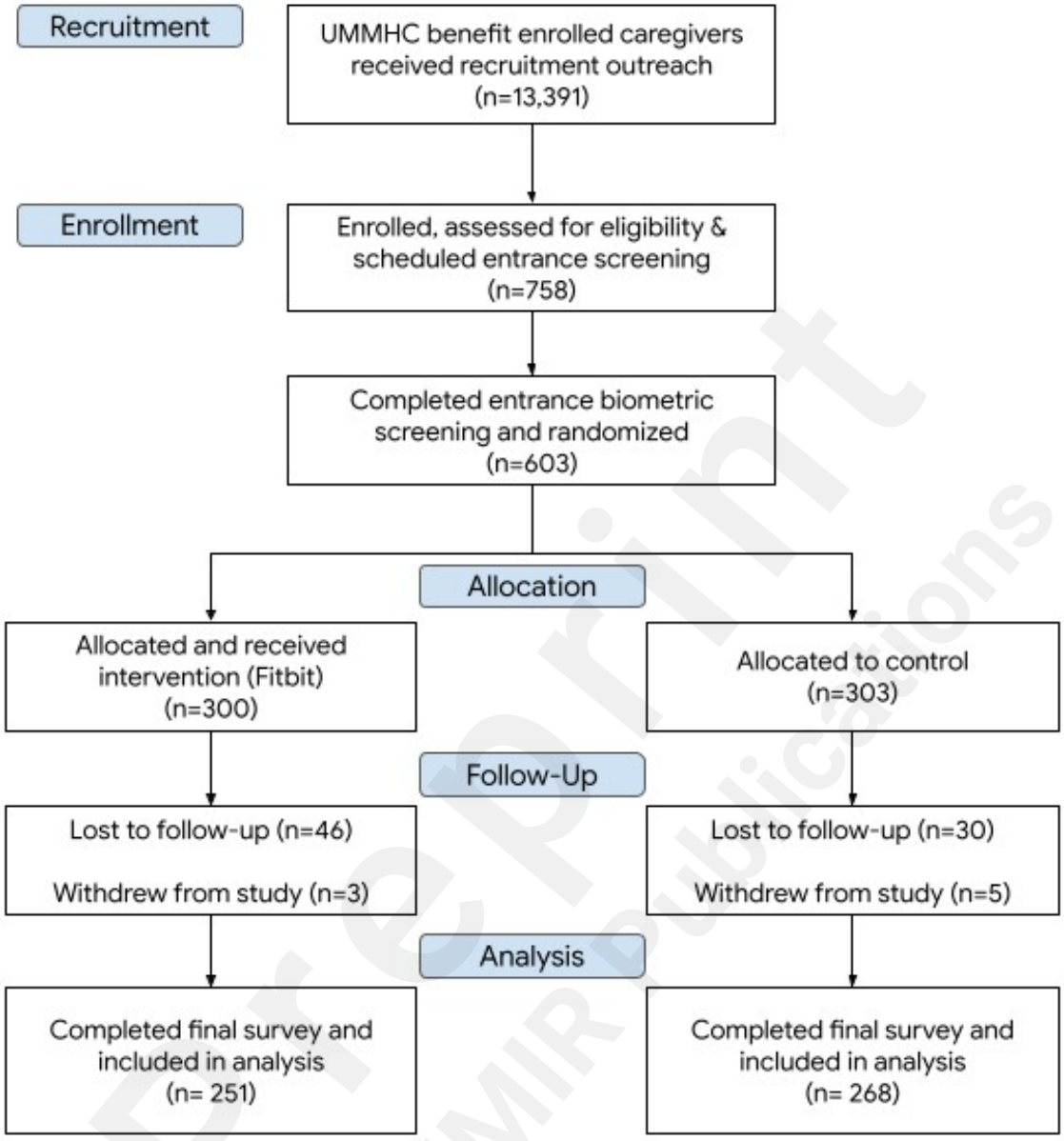

Figure 3. Sample screenshots of Fitbit Premium features: Rich video content including workouts (left) and advanced analytics including Sleep Score (right).

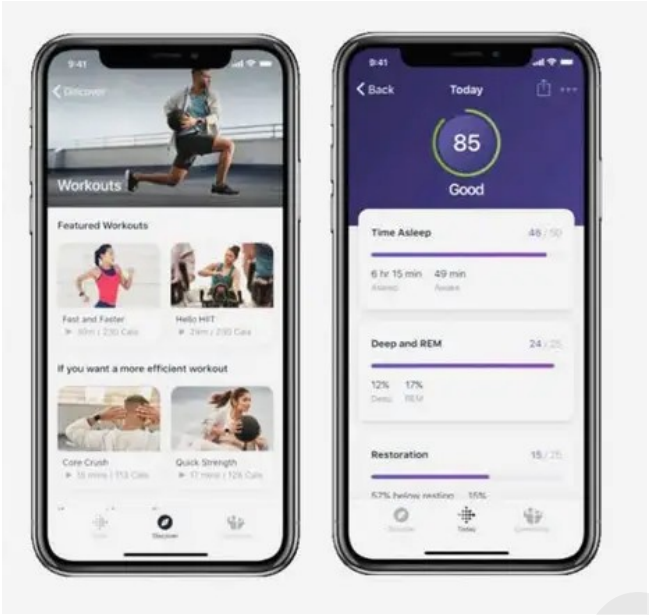

Figure 4: Sample screenshot of On-Demand Health Coaching features: The participant and coach collaboratively create an action plan for stress management. The user can click on the coach's profile to learn more about their background or click on the messaging button to chat securely and asynchronously.

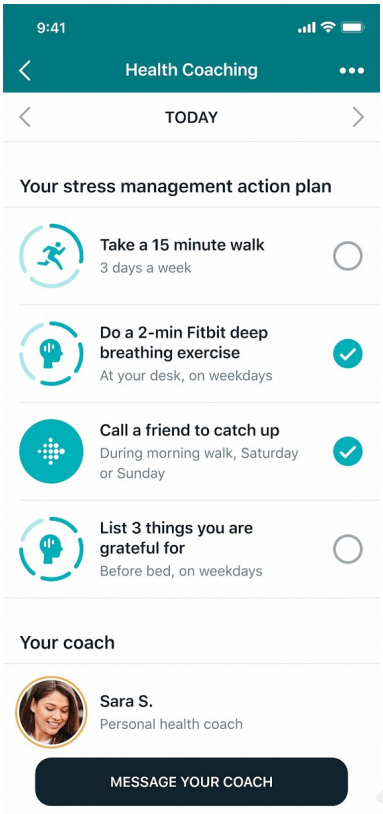

Figure 5. Data collection schedule

	STUDY PERIOD (Jan - Dec 2021)						Post-study
	Enrollment	Allocation	Post-allocation			Close-out	
Events and procedures	Visit 0	Visit 1	3 months	6 months	9 months	12 months / Visit 2	
ENROLLMENT							
Informed consent	X						
Demographics	X						
Eligibility confirmation	X						
Allocation		X					
ASSESSMENT							
Biometric screening (height, weight, waist circumference, blood pressure, etc.) - Quest Diagnostics		X				X	
Baseline survey (nutrition, exercise, sleep, and mindfulness habits) - REDCap	X						
Quarterly survey (nutrition, exercise, sleep, and mindfulness habits) - REDCap			X	X	X	X	
Two years of Total Medical Expenditure claims data - Conifer Health Solutions							X
INTERVENTION							
Onboarding survey for coaching component		X					
Engagement data for each component of intervention		Continuous collection of device wear duration Event-based collection of app-open events, feature usage (including Fitbit Premium features), secure messages with coach, etc.					
Wearable device and weight scale data		Continuous collection of wearable device data (steps, resting heart rate, sleep metrics, etc.) Event-based collection of weight data					

Figure 6. Conceptual framework of Fitbit's multimodal digital behavior change intervention (DBCI) for improving healthy behaviors and cardiometabolic outcomes. Components of Fitbit's DBCI depicted in blue boxes. The framework represents a combination of the Health Belief Model and framework proposed by Bodai, et. al. [45]

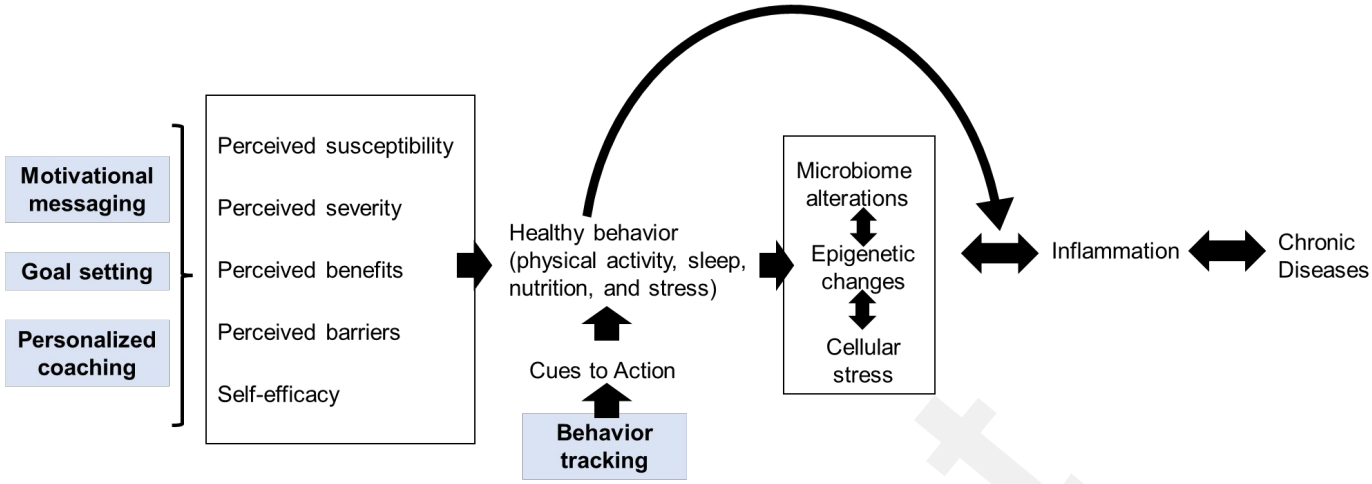

Table 1. Baseline participant characteristics

Characteristics	Intervention	Control	p-value
Number of participants	300	303	
Age in years, mean (SD)	46.3 (11.0)	47.2 (11.4)	0.34
Gender, n (%)			
Female	241 (80.3)	243 (80.2)	0.50
Race, n (%)			
White	254 (86.1)	250 (84.8)	0.80
Black/African-American	11 (3.7)	9 (3.1)	
Asian	20 (6.8)	22 (7.5)	

Other	10 (3.4)	14 (4.8)	
Ethnicity, n (%)			
Hispanic	16 (5.3)	25 (8.3)	0.34
Non-Hispanic	277 (92.3)	270 (89.1)	
No answer	7 (2.3)	8 (2.6)	
BMI Classification, n (%)			
Underweight	3 (1.0)	2 (0.7)	0.56
Normal	65 (21.9)	78 (26.8)	
Overweight	100 (33.7)	91 (31.3)	
Obese	129 (43.4)	120 (41.2)	
Biometric Measurements, mean (SD)			
Weight, lbs.	185.5 (46.9)	178.4 (43.7)	0.06
Height, in.	65.5 (3.5)	65.2 (3.3)	0.26
BMI	30.4 (7.1)	29.5 (6.7)	0.12
Waist circumference, in.	37.6 (6.5)	36.4 (6.0)	0.02
Systolic BP	121.0 (9.6)	119.2 (10.2)	0.03
Diastolic BP	75.2 (8.0)	74.3 (7.9)	0.17
HbA1c	5.2 (0.6)	5.2 (0.5)	0.47
Total cholesterol	190.6 (38.7)	196.8 (38.0)	0.05
HDL-C	58.0 (14.5)	59.3 (14.7)	0.29
LDL-C	118.7 (34.5)	123.5 (34.6)	0.10
TC/HDLratio	3.5 (1.0)	3.5 (1.2)	0.57

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Ethics approval and consent to participate: This study was approved by UMass Chan Medical School IRB (Docket number- H-00021669).

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Google employees and own stock at Alphabet.

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Data Availability: The data sets analyzed during the current study are available from the corresponding author on reasonable request. Due to the collection of participant health information, we do not have plans for granting public access to participant level datasets.

Author Contributions: SHW and AS wrote the manuscript. JM developed the concept and design of the study. JHC, MH, and BB provided critical revisions for important intellectual content. PL, DA, and BB performed the statistical analysis for the manuscript. Supervision provided by AS, JM, DM. Logistical support provided by PL, SG, and NH. All authors reviewed the final manuscript and are in agreement with authorship contributions. We used the generative AI tool ChatGPT by OpenAI for editing purposes on April 22, 2024.

Abbreviations: Active Zone Minutes (AZM), Digital Behavior Change Intervention (DBCI) Randomized Controlled Trial (RCT), UMass Memorial Health (UMMH), Personal Health Information (PHI), US Preventive Services Task Force (USPSTF)

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Supplementary Files

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Figures

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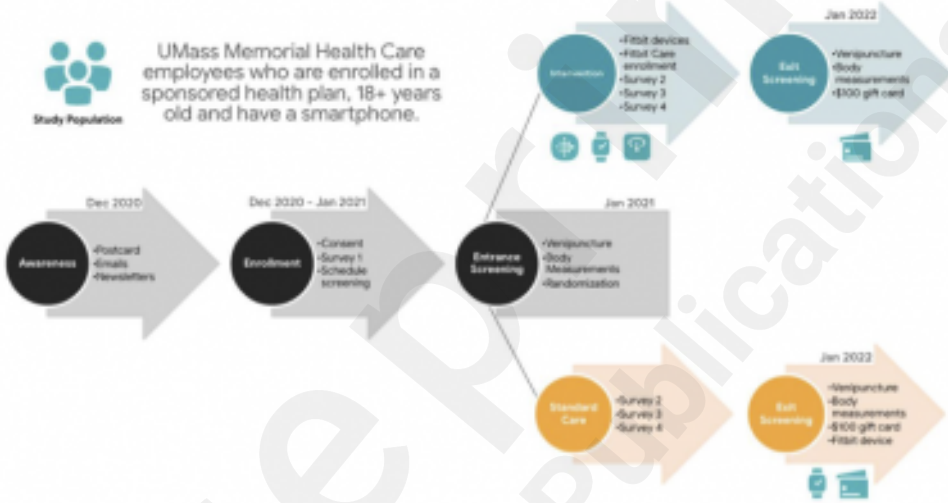
Tables and Figures

Figure 1. UMass Fitbit Care Study Design: Health behavior data was collected through baseline and quarterly online surveys, while biometric measurements were obtained during clinic visits at baseline and at the 12-month follow-up. The exit screening phase concluded in January 2022.



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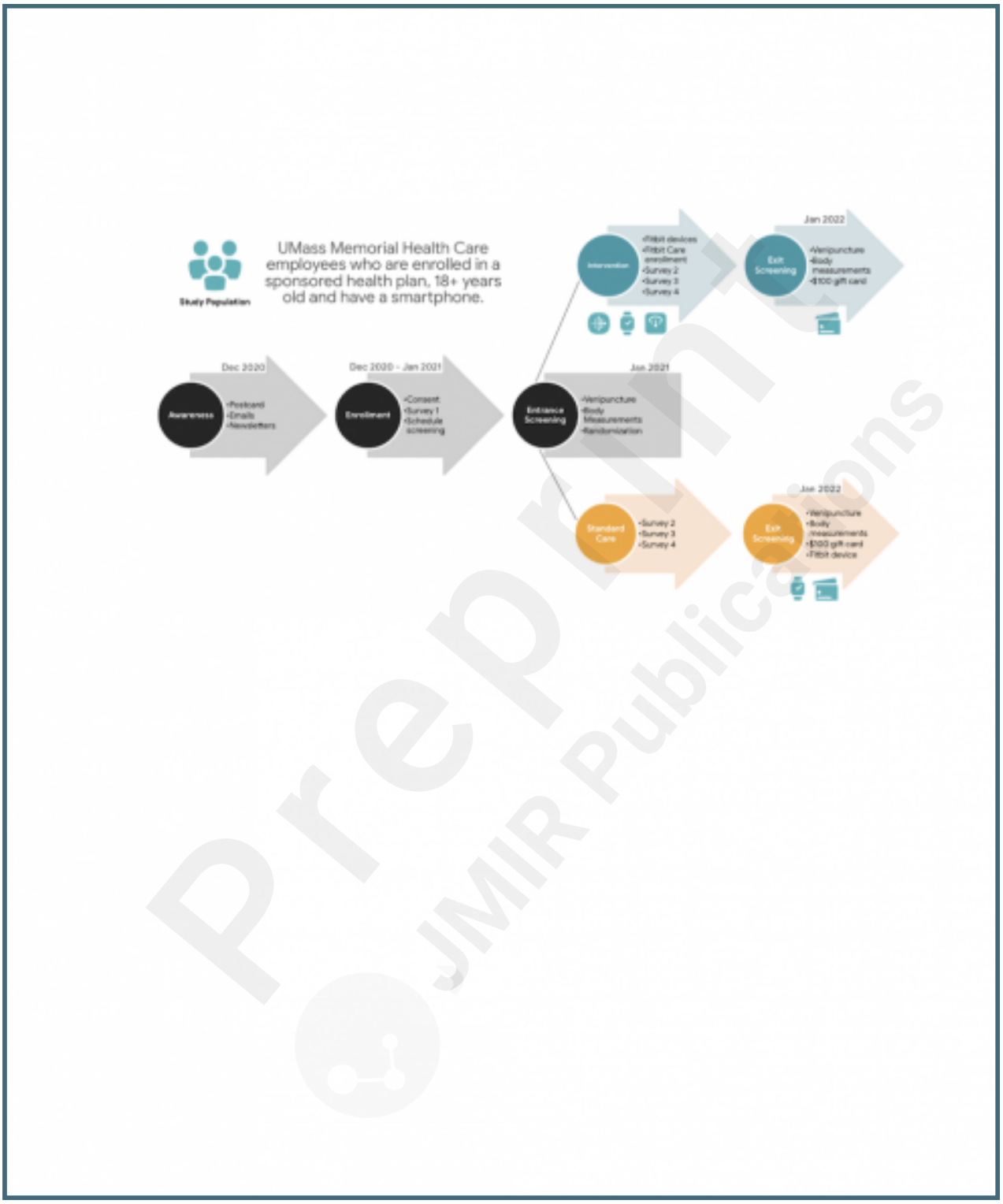
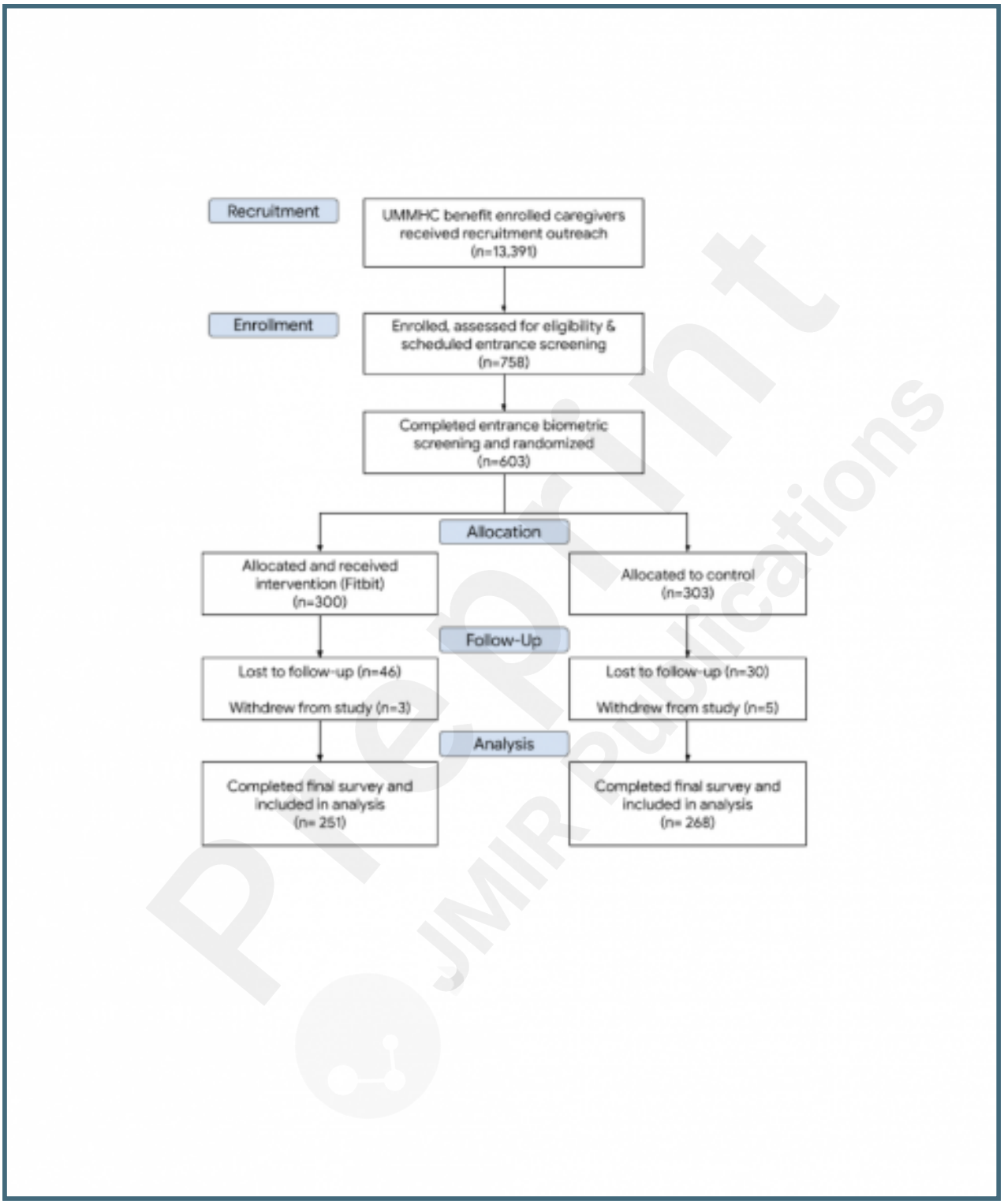
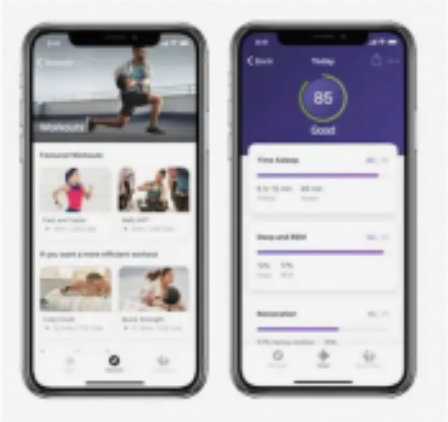


UMass Fitbit Care Study Participant Flow.



Sample screenshots of Fitbit Premium features: Rich video content including workouts (left) and advanced analytics including Sleep Score (right).



Sample screenshot of On-Demand Health Coaching features: The participant and coach collaboratively create an action plan for stress management. The user can click on the coach's profile to learn more about their background or click on the messaging button to chat securely and asynchronously.

Data collection schedule.

	STUDY PERIOD (Jan - Dec 2021)						Post-study
	Enrollment	Allocation	Post-allocation			Close-out	
Events and procedures	Visit 0	Visit 1	3 months	6 months	9 months	12 months / Visit 2	
ENROLLMENT							
Informed consent	X						
Demographics	X						
Eligibility confirmation	X						
Allocation		X					
ASSESSMENT							
Biometric screening (height, weight, waist circumference, blood pressure, etc.) - Quest Diagnostics		X				X	
Baseline survey (nutrition, exercise, sleep, and mindfulness habits) - RedCap	X						
Quarterly survey (nutrition, exercise, sleep, and mindfulness habits) - RedCap			X	X	X	X	
Two years of Total Medical Expenditure claims data - Conifer Health Solutions							X
INTERVENTION							
Onboarding survey for coaching component		X					
Engagement data for each component of intervention		Continuous collection of device wear duration Event-based collection of app-open events, feature usage (including Fitbit Premium features), secure messages with coach, etc.					
Wearable device and weight scale data		Continuous collection of wearable device data (steps, resting heart rate, sleep metrics, etc.) Event-based collection of weight data					

Multimedia Appendixes

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