An Exploration of the Effectiveness of the Fun For Wellness Online Intervention to Promote Health in Adults with Obesity: A Randomized Controlled Trial

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Abstract

2	Fun For Wellness (FFW) is an online behavioral intervention developed to promote well-being
3	by enhancing the self-efficacy of participants. The objective of this study was to evaluate the
4	effectiveness of FFW to promote health in adults with obesity in the United States of America in
5	a relatively uncontrolled setting. The study design was a large-scale, prospective, double-blind,
6	parallel group randomized controlled trial. Data collection occurred at three time points:
7	baseline, 30 days, and 60 days after baseline. There was evidence for a positive direct effect of
8	FFW on physical health status ($\hat{\beta} = 1.33$, $p = .005$, $d = 0.24$) at 60 days after baseline. In
9	addition, there was evidence of a positive indirect effect of FFW on mental health status at 60
10	days after baseline through psychological well-being self-efficacy ($\hat{\beta} = 0.44$, [0.05, 0.94]).
11	Keywords: e-Health, m-Health, self-efficacy theory, well-being, health promotion,
12	physical well-being self-efficacy, psychological well-being self-efficacy, mediation, physical
13	health status, mental health status

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Approximately one-third of adults who are overweight can more precisely be classified as 16 adults with obesity, and the size of this sub-group has tripled over the past few decades (World 17 Health Organization, 2018). Globally, it is estimated that two billion adults are overweight 18 (WHO, 2018). This trend is problematic because people with obesity may be at risk for major 19 non-communicable chronic diseases such as cardiovascular disease, type II diabetes, 20 musculoskeletal disorders, and some cancers (United States Department of Health and Human 21 22 Services [USDHHS], 2013). To reduce the prevalence of adults with obesity, the WHO (2018) recommends that individuals engage in regular physical activity (e.g., 150 minutes at moderate 23 intensity per week). Unfortunately, there is evidence that a very small percentage (e.g., < 5%) of 24 adults with obesity meet public health guidelines for physical activity (Tudor-Locke et al., 2010). 25 Fortunately, there is also evidence that cognitive-behavioral interventions can successfully 26 promote physical activity in adults with obesity (Gourlan et al., 2011). To encourage sustained 27 engagement in physical activity, the potential for experiencing health benefits across a broad 28 array of health dimensions may be targeted and emphasized (Sullivan et al., 2001; USDHHS, 29 2013). Focused interventions for populations at risk are an established practice in prevention 30 science (e.g., United States Preventive Services Task Force, 2018). 31

The objective of the current study was to evaluate the effectiveness of the Fun For Wellness (FFW) intervention to increase the physical and mental health of adults with obesity in the United States of America (USA), in a relatively uncontrolled setting. This is a population that could benefit from more resources, not just in improving physical health, but also in emotional well-being. The study described here was conceptualized as an effectiveness trial that built upon

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a FFW efficacy trial completed in a relatively controlled setting (i.e., adult employees at a major
research university in the USA) (Myers, Prilleltensky, Prilleltensky, et al., 2017). The present
investigation is significant because the potential benefits of interventions should be evaluated
under both ideal (e.g., more controlled) and real-world (e.g., less controlled) conditions (Singal
et al., 2014). Prior to reporting the findings from the FFW efficacy trial and the hypotheses in the
current study, we describe our theory of change, the promise of online interventions, and the
rationale for the study.

44 Self-Efficacy

FFW is informed by self-efficacy theory (Myers, Prilleltensky, Hill, & Feltz, 2017). 45 According to this theory, the beliefs held by individuals about their ability to perform certain 46 actions can affect outcomes related to physical and mental health (Bandura, 1997). Self-efficacy 47 beliefs rely upon four primary sources: enactive mastery experiences, vicarious experiences, 48 verbal persuasion, and physiological and/or emotional states. In FFW, enactive mastery 49 experiences derive from playing and mastering interactive games. Participants are exposed to 50 vicarious experiences of self-efficacy when they watch vignettes performed by professional 51 actors. Verbal persuasion is experienced through exposures to mini-lectures by coaches. Finally, 52 participants can derive a feeling of self-efficacy through physiological and emotional responses 53 to self-reflection exercises. The scientific literature supporting each of these proposed sources of 54 self-efficacy information in physical activity contexts is reviewed in Feltz et al. (2008). 55 56 Furthermore, targeting self-efficacy as a potentially modifiable mediating variable via intervention is an established practice in prevention science (e.g., MacKinnon et al., 2001; 57 58 Payton et al., 2000).

59 **Online Interventions**

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Although face-to-face preventive interventions are effective in addressing mental and
physical health conditions (Conley et al., 2015; Nelson et al., 2015; Prilleltensky & Nelson,
2013), they are limited in reach and very labor intensive. Online interventions, in turn, offer
many benefits in the promotion of healthy behaviors and the prevention of adverse conditions:
scalability, interactivity, affordability, accessibility, and fidelity of implementation (Moessner et
al., 2015; Portnoy et al., 2008; Proyer et al., 2014).

There is evidence that online preventive programs are effective. In a review of 66 randomized controlled trials, researchers found that online programs improved knowledge, 67 attitudes, intentions and behaviors associated with tobacco use, substance use, nutrition, eating 68 disorders, and sexual behaviors (Portnoy et al., 2008). In an internet program aimed at reducing 69 stress and promoting physical activity, meaningful improvements were found in overall well-70 being, emotional health, physical health, healthy behaviors, and life evaluations (Prochaska et al., 71 2012). Other studies have shown the efficacy of web-based and mobile interventions in areas 72 such as drug abuse prevention (Schwinn et al., 2010), eating disorders (Moessner et al., 2015), 73 and emotional well-being (Cobb & Poirier, 2014; Prover et al., 2014). 74

75 Fun For Wellness

Depending both on readiness (Norcross, 2012) and individual differences in change strategies (Dolan, 2014; Klingemann & Sobell, 2007), some people relate better to certain strategies than to others. Therefore, we found it necessary to create an intervention that would incorporate a variety of strategies and modes of learning. With regard to the latter, FFW incorporates skill building and scenario-based learning, which are superior to didactic methods (Conley et al., 2015; Irvine et al., 2015). FFW utilizes several learning modalities, including case studies with real actors, video games, mini-coaching sessions, reflection exercises, and humor.

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Each activity is called a challenge. In total, there are 152 challenges in FFW (for more details on 83 the intervention, please see Myers, Prilleltensky, Lee, et al., 2019 and Myers, Prilleltensky, 84 Prilleltensky, et al. 2017). The challenges derive from a model of change summarized in the 85 acronym BET I CAN, which stands for Behaviors, Emotions, Thoughts, Interactions, Context, 86 Awareness, and Next Steps. These are conceptualized as drivers of change because each one can 87 be leveraged to modify a habit, thought, or emotion to exert a positive impact on well-being. 88 Each BET I CAN driver of change is taught to participants through two specific skills: 89 behaviors (how to set a goal and how to create positive habits), emotions (how to cope with 90 91 negative emotions and how to cultivate positive emotions), thoughts (how to challenge negative assumptions and how to create a new narrative about our lives), *interactions* (how to connect and 92 how to communicate), *context* (how to read cues and how to change cues in the environment), 93

94 *awareness* (how to know yourself and how to know the issue), and *next steps* (how to make a

plan and how to make it stick). For example, under *emotions*, participants are taught how to 95 cultivate positive emotions through savoring, gratitude, and mindfulness. Under behaviors 96 participants are taught how to set an achievable goal such as exercising daily and eating more 97 fruits and vegetables. Under *thoughts*, participants are taught how to develop a growth mindset 98 99 and combat a fixed mindset. Under *interactions*, they are taught active listening. Each challenge or activity lasts approximately two to four minutes. Participants have access to FFW 24/7. The 100 software keeps track of the user's progress and engagement with the program. A progress bar in 101 102 the form of a thermometer shows participants how much they have accomplished already and how much is left in the program. All told, the program is about 12 hours long. 103

Hitherto, FFW has shown positive results in certain domains of health with a population
of healthy adults and with a population of people with obesity. With regard to the former, a

106	randomized controlled trial demonstrated that the program was instrumental in enhancing
107	psychological, interpersonal, community, and economic subjective well-being (Myers,
108	Prilleltensky, Prilleltensky, et al., 2017). These outcomes were measured using the I COPPE
109	scale (Prilleltensky et al., 2015), which evaluates satisfaction with different life domains. In
110	addition, FFW generated actions to promote well-being in the interpersonal and physical
111	domains of health (Myers, Dietz, et al., 2018). Specifically, participants reported engaging in
112	wellness-enhancing behaviors such as eating more fruits, vegetables and legumes; exercising
113	more; and nurturing relationships. Finally, FFW increased well-being self-efficacy (Myers,
114	Prilleltensky, Hill, & Feltz, 2017). This means that participants reported more confidence in their
115	ability to undertake actions to promote their own wellness.
116	With regard to the population of people with obesity, a second RCT with FFW showed
117	that participants increased their self-efficacy in terms of physical activity, and that, in turn, self-
118	efficacy increased their actual physical activity (Myers, McMahon, et al., 2020). In addition,
119	FFW improved community, occupational, physical, and psychological wellness (Myers,
120	Prilleltensky, et al., 2020). This study measures the impact of FFW on the physical and mental
121	well-being of participants.

122 Summary and Rationale for Present Study

In light of previous positive results using FFW with the general population and with people with obesity, and in light of the many health risks faced by the latter, this study sought to ascertain whether FFW can enhance physical and mental health within this population. In addition, given that previous studies have shown that self-efficacy is an important mediator in achieving positive health outcomes, we wanted to examine its role in fostering physical and mental health in people with obesity. Specifically, we wanted to study (a) whether FFW can have

a direct effect on the physical and mental health of people with obesity, and (b) whether self-129 efficacy can play a role in these outcomes as a mediating variable. Figure 1 displays our 130 conceptual model. Whereas previous studies using FFW measured subjective well-being 131 outcomes with the I COPPE scale (Prilleltensky et al., 2015), the present investigation uses as the 132 main outcome the 36-item OptumTM SF-36v2 Health Survey (Ware, 2000; Ware & Kosinski, 133 1996). It was important for us to test in this study the effects of FFW using metrics that examine 134 not just subjective well-being, as does the I COPPE scale, but also symptomatology related to 135 physical and mental health status. This is why we chose to focus this study on the OptumTM SF-136 36v2 Health Survey. 137

138 Hypotheses

Four exploratory hypotheses were investigated in the current study based on the 139 conceptual model depicted in Figure 1. Hypothesis 1 was that the FFW intervention would exert 140 a positive direct effect on well-being self-efficacy. Hypothesis 2 was that well-being self-141 efficacy would exert a positive direct effect on health. Hypothesis 3 was that the FFW 142 intervention would exert a positive direct effect on health. Hypothesis 4 was that the FFW 143 intervention would exert a positive indirect effect on health through well-being self-efficacy. 144 Dimension-specific hypotheses for physical and mental health status were not made due to a lack 145 of previous research on the effectiveness of the FFW intervention with this particular population. 146 147 Method 148 All procedures in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 149

150 Helsinki declaration and its later amendments or comparable ethical standards. The institutional

review board at the University of Miami provided necessary permission (IRB# 20170541) to

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conduct this study on July 11, 2017. The University of Miami and Michigan State University 152 (STUDY00000979) established an Institutional Authorization Agreement on June 26, 2018 that 153 provided permission for the University of Miami to serve as the designated IRB for this study. 154 **Trial Registration** 155 The data described in this manuscript were collected within a broader clinical trial, the 156 Well-Being and Physical Activity Study (ClinicalTrials.gov, identifier: NCT03194854). Within 157 this section we provide an overview of the relevant methods used in the Well-Being and Physical 158 Activity Study to provide a context for the specific focus of this manuscript (American 159 Psychological Association, 2010). Readers are referred to Myers et al. (2019) for a fuller 160 description of the protocol for the Well-Being and Physical Activity Study. A populated 161 CONSORT (Consolidated Standards of Reporting Trials)-EHEALTH checklist was provided for 162 the Well-Being and Physical Activity Study by Myers, McMahon, Prilleltensky et al. (2020). 163 who reported on the physical activity outcome data. The health outcome data that are the primary 164 focus of this manuscript have not been considered in any previous report. The demographic 165 covariates and compliance data briefly reported in subsequent sections of this manuscript, 166 however, have also been reported by Myers, McMahon, Prilleltensky et al. (2020). See also 167 168 Table 1.

169 Study Design

The study design was a large-scale, prospective, double-blind, parallel group randomized controlled trial (RCT). Recruiting, screening, random assignment and collection of data were conducted online from August 2018 through November 2018. Data collection occurred at three time points: baseline (T1), 30 days (T2) and 60 days (T3) after baseline. The timeline for this study was similar to timelines used in other well-being (Hendriks et al., 2019) and physical
activity (de Vries et al., 2016) interventions.

176 Recruitment and Eligibility

A sample size of approximately nine hundred participants was targeted for enrollment in 177 the study. Participants were recruited through the general population panel of the SurveyHealth 178 (http://www.surveyhealthcare.com/) recruitment company. Partnering with a panel recruitment 179 company is consistent with recruitment in preliminary research on FFW (e.g., Prilleltensky et al., 180 2015) and with a movement toward larger and smarter health promotion interventions (Bauer et 181 al., 2014; Reis et al., 2016). Eligibility criteria were: (a) ability to access the online intervention, 182 (b) living in the USA, (c) 18 years old \leq age \leq 64 years old, (d) body mass index \geq 25.00 183 kg/m^2 , and (e) absence of simultaneous enrollment in another intervention program promoting 184 either well-being or physical activity. The BMI criterion included the overweight (i.e., 25.00-185 29.99 kg/m²) category consistent with many physical activity-promoting interventions for adults 186 with obesity (Gourlan et al., 2011). 187

188 Informed Consent

Informed consent was obtained from each participant included in the study. More specifically, immediately after being determined to be eligible for this study, each eligible individual was directed to a web-based, IRB-approved informed consent form. Each individual who clicked "Consent to Participate" was enrolled as a participant in the study. Each individual who clicked "Decline to Consent" was denied access to any further study-related activities. It is worth noting that participants were not required to engage in strenuous physical activity. The program was strictly psychoeducational and did not demand from participants to engage in any

196 physical activity. They were encouraged to do so, but it was not requested. Furthermore,

197 participants read a medical disclaimer explaining that FFW does not replace medical care.

198 Random Assignment

Random assignment of each eligible participant occurred after (a) a unique and secure 199 login credential was created, (b) informed consent was obtained, (c) a medical disclaimer was 200 agreed to, and (d) the T1 survey battery was completed. Eligible participants were randomly 201 assigned to the intervention (i.e., FFW) or the usual care (i.e., UC) group via software code that 202 was written to accomplish equal allocations to the FFW and UC groups. Participants assigned to 203 the FFW group were given immediate access to the intervention. Participants assigned to the UC 204 group were put on a waitlist for access to the intervention. Please see Table 1 for further details 205 on the demographic composition of our sample. 206

207 Usual Care. Participants assigned to the UC group were asked to conduct their lives as usual.

208 The login credential for each UC participant provided access to a secure website to complete the

survey battery at T1, T2, and T3. Usual care participants had the opportunity to earn up to \$30

210 worth of Amazon electronic gift cards. Specifically, UC participants could earn \$5 for

completing the T1 survey battery, \$10 for completing the T2 survey battery, and \$15 for

completing the T3 survey battery. Usual care participants were given one month of 24-hour

access to the FFW intervention after data collection for this study was closed.

214 Fun For Wellness. Participants assigned to the FFW group were asked to engage with the FFW

215 intervention. The login credential for each FFW participant provided 30 days (i.e., from T1 to

T2) of 24-hour access to the 152 BET I CAN challenges, as well as access to a secure website to

complete the survey battery at T1, T2, and T3. Fun for Wellness participants had the opportunity

to earn a total of \$45 worth of Amazon electronic gift cards. Specifically, FFW participants

could earn \$5 for completing the T1 survey battery, \$10 for completing both the T2 survey

battery and at least 15 BET I CAN post-introductory challenges (plus an additional \$15 for

completing at least 30 BET I CAN post-introductory challenges), and \$15 for completing the T3
 survey battery.

Participants were required to complete four introductory challenges in order to gain 223 access to the remaining 148 post-introductory BET I CAN challenges. These introductory 224 challenges provided an orientation to the website and to the characters that appear in the 225 vignettes. Participants self-selected which post-introductory BET I CAN challenges to complete. 226 Challenges completed by each participant were tracked by computer software to provide data 227 (i.e., participation points) for the FFW engagement scoring system (Myers, Prilleltensky, 228 Prilleltensky, et al., 2017). Earning at least 21 participation points was the operational definition 229 for being engaged with the FFW intervention (Myers et al., 2019). 230

231 Survey Battery

Instruments designed to measure demographic information, well-being self-efficacy, and health were included in the survey battery. Proposed demographic covariates of well-being were collected via self-report at T1 and included participant gender, race/ethnicity, highest level of education completed, marital status, employment status, age, and household annual income (Rubenstein et al., 2016). This set of demographic variables is collectively referred to as the demographic covariates from this point forward.

Health. Health was measured at T1 through T3 with the well-established 36-item

239 OptumTM SF-36v2 Health Survey (Ware, 2000; Ware & Kosinski, 1996). Summary measures

comprising two components, physical health status ($\alpha = .89$) and mental health status ($\alpha = .82$),

241 were derived from previous psychometric reports (Ware et al., 1994; Ware et al., 1995; Ware et

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al., 1998; Ware et al., 2007). From an empirical perspective, the two-component scoring 242 approach (physical and mental health) offered more precision than the eight-health-domain 243 scoring approach (Maruish, 2011). From a conceptual perspective, the two-component scoring 244 approach better aligned with the focus of the FFW intervention because the intervention targets 245 both physical and mental health and not necessarily some of the other domains such as bodily 246 pain and social functioning. The physical health status component asks participants about their 247 ability to engage in physical activities such as carrying groceries, climbing stairs, and walking a 248 mile. In addition, it asks about feeling sick and changes in their health. The mental health status 249 component, among other things, asks about feeling nervous, depressed, happy, and peaceful. 250 Well-Being Self-Efficacy. Instead of using a general self-efficacy measure, our team developed a 251 specific well-being self-efficacy measure, which is, according to various authors, the preferred 252 mode of assessing self-efficacy (Bandura, 2006; Myers, Prilleltensky, Hill, & Feltz, 2017; 253 Myers, McMahon, Prilleltensky, et al., 2020). Our measure, as we shall explain below, measures 254 physical well-being self-efficacy and psychological well-being self-efficacy separately. 255 Well-being self-efficacy was measured at T1 through T3 with two subscales, the physical 256 well-being self-efficacy ($\alpha = .77$) and the psychological well-being self-efficacy ($\alpha = .78$) of the 257 Well-Being Self-Efficacy (WBSE) Scale (Myers, Prilleltensky, Hill, & Feltz, 2017; Myers et al., 258 2019). Physical well-being self-efficacy was defined as the degree to which individuals perceive 259 that they have the capability to attain well-being in their physical health and wellness. 260 Psychological well-being self-efficacy was defined as the degree to which individuals perceive 261 that they have the capability to attain well-being in their psychological and emotional 262 experiences. Each of the two subscales has a unique item stem asking participants about their 263 perceived capability in each domain in three different time periods: past (30 days ago), present 264

(right now), and future (30 days from now). This 6-item version of the WBSE Scale was 265 concordant with health as conceptualized in the FFW context (i.e., physical health status and 266 mental health status) based on guidelines for the construction of self-efficacy scales (Bandura, 267 2006). Both of these dimensions of well-being self-efficacy had an exclusive item stem that 268 referenced three unique periods of time: past (i.e., 30 days ago), present (i.e., right now), and 269 future (i.e., 30 days from now). The exclusive item stem for physical well-being self-efficacy 270 was "your physical health and wellness." The exclusive item stem for psychological well-being 271 self-efficacy was "your psychological and emotional well-being." Responses to each item were 272 organized within a five-category rating scale structure, where $0 = n_0$, 1 = low, 2 = moderate, 3 =273 high, and 4 = complete confidence, based on previous psychometric research on effective self-274 efficacy rating scale structures (Myers et al., 2008). 275

276 Data Analytic Approach

A path model was fitted in Mplus 8.4 with maximum-likelihood (ML) estimation with 277 robust standard errors (Muthén & Muthén, 1998-2017). Type I error rate was set equal to .05. 278 Missing data were addressed with full information ML estimation using the observed 279 information matrix under the assumption of missing at random (MAR; Schafer & Graham, 280 2002). Indexes of model-data fit considered were: the exact fit test (χ_R^2) , root mean square error 281 of approximation (RMSEA), standardized root mean square residual (SRMR), comparative fit 282 index (CFI), and the Tucker-Lewis index (TLI) consistent with relevant recommendations (e.g., 283 Kline, 2016). Latent variable reliability was measured with coefficient H (Hancock & Mueller, 284 2001). Component score reliability was assessed with Cronbach's alpha (Cronbach, 1951; 285 Raykov & Marcoulides, 2019). Indexes of effect size for direct effects on component score 286 variables were Cohen's d (1988) and percentage of observed variance explained. Indexes of 287

effect size for direct effects on latent variables were latent mean difference (Hancock, 2001) and 288 percentage of latent variance explained. The latent mean difference coefficient is an analog to 289 Cohen's d (1988) and also is denoted as d from this point forward. Commonly used heuristics 290 were used to assist in the interpretation of an absolute value of Cohen's d: .20 (small), .50 291 (medium), and .80 (large). For each indirect effect a bias-corrected bootstrapped estimate of the 292 95% confidence interval (CI) was obtained with the number of draws set equal to 2000 293 (MacKinnon, 2008). An index of effect size was not considered for indirect effects because an 294 effect size index for complex mediation models with latent variables has not yet been established 295 (Lachowicz et al., 2018). 296 **Path Model.** An over-identified (df = 212) path model was fitted to the data consistent with the 297 conceptual model depicted in Figure 1 under an intent-to-treat approach (Hollis & Campbell, 298 1999). Latent physical well-being self-efficacy at T2 was regressed on FFW (i.e., a dummy 299 coded variable, where 0 = UC, 1 = FFW), latent physical well-being self-efficacy at T1, physical 300 health status at T1, and demographic covariates. Latent psychological well-being self-efficacy at 301 T2 was regressed on FFW, latent psychological well-being self-efficacy at T1, mental health 302 status at T1, and demographic covariates. Physical health status at T3 was regressed on FFW, 303 latent physical well-being self-efficacy at T2, physical health status at T1, and demographic 304 covariates. Mental health status at T3 was regressed on FFW, latent psychological well-being 305 self-efficacy at T2, mental health status at T1, and demographic covariates. The expression 306 "adjusted (latent) mean difference," is used from this point forward to acknowledge the statistical 307 adjustment made by including covariates in the model. Each of the four latent variables had three 308 unique indicators. 309

There were four sets of focal parameters in the path model. The first set of focal 310 parameters was the direct effects of FFW on the two domains of latent well-being self-efficacy at 311 T2 (i.e., β_1). Each of these two parameters was interpreted as the adjusted mean difference on 312 latent well-being self-efficacy (i.e., physical or psychological) at T2 for the FFW group as 313 314 compared to the UC group. The second set of focal parameters was the direct effects of the two domains of latent well-being self-efficacy at T2 on the corresponding health status at T3 (i.e., 315 β_2). Each of these two parameters was interpreted as the path coefficient from a particular 316 domain of latent well-being self-efficacy (e.g., physical) at T2 to the corresponding health status 317 (e.g., physical) at T3. The third set of focal parameters was the direct effects of FFW on the two 318 health statuses at T3 (i.e., β_3). Each of these parameters was interpreted as the adjusted mean 319 difference on health status (i.e., physical or mental) at T3 for the FFW group as compared to the 320 UC group. The fourth set of focal parameters was the indirect effects of FFW on the two health 321 statuses at T3 through the corresponding domain of latent well-being self-efficacy at T2 (i.e., β_4 , 322 where $\beta_4 = \beta_1 \ast \beta_2$). Each of these two parameters was interpreted as the product of path 323 coefficients from FFW to a particular health status (e.g., mental) at T3 through the corresponding 324 325 domain of latent well-being self-efficacy (e.g., psychological) at T2. Each set of focal parameters tested the numerically corresponding hypothesis (e.g., β_1 tested hypothesis 1). 326 *Necessary Sample Size.* Necessary sample size was determined for a fixed level of power for 327 rejecting the null hypothesis that the population model-data fit of the path model was at or 328 exceeded a particular value for poor model-data fit (MacCallum et al., 1996) using an online 329 330 utility (Preacher & Coffman, 2006) consistent with relevant recommendations (Myers, Ntoumanis, et al., 2018). Population model-data fit (i.e., ε) in the RMSEA metric was set equal 331 to .05 in the null condition (i.e., ε_0), which defined the boundary for poor model-data fit. Two 332

values of population model-data fit were specified, .02 and .04, in the alternative condition (i.e., ϵ_1). Type I error was set equal to .05. Degrees of freedom were set equal to 212. Power was set equal to .80. When $\epsilon_1 = .02$ necessary sample size was equal to 137. When $\epsilon_1 = .04$ necessary sample size was equal to 455.

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Results

338 Participant Characteristics

Figure 2 depicts participant flow from eligibility screening to randomization to retention 339 over the three measurement occasions for the health outcome data. A total of 821 consented 340 participants were randomly assigned to FFW (n = 410) or UC (n = 411). Forensic analysis by a 341 computer scientist done prior to data analysis identified 154 cases as fraudulent and these cases 342 were excluded from analysis leaving 667 analyzed cases (i.e., participants), FFW (n = 331) or 343 UC (n = 336). The researchers initiated the forensic analysis and then consulted with the 344 designated IRB, legal counsel, and the office of research compliance and quality assurance about 345 the computer scientist's report of suspicious activity on the website (e.g., participants logging in 346 very close temporal proximity and sending identical e-mails to the computer scientist in 347 inadequate English). The forensic analysis revealed that all of these 154 accounts were made by 348 one user and/or group through two virtual private server services. The analysis was reported as a 349 Reportable New Information (RNI#00003760) incident to the designated IRB in December 2018. 350 An exploratory logistic regression model with the demographic covariates specified as 351 predictors provided evidence that the Hispanic variable (i.e., b = 1.00, p = .030) and the age 352 variable (i.e., b = 0.05, p = .002) were significant predictors of missing data (i.e., 0 = not353 missing, 1 = missing) at T2, while the Hispanic variable (i.e., b = 1.00, p = .030), the age 354 variable (i.e., b = 0.05, p = .002), and the married variable (i.e., b = -0.76, p = .047) were 355

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observing missing data within the FFW group at T2 and T3 increased with age and were higher 357 for participants who identified as Hispanic, while the odds of observing missing data at T3 were 358 lower for participants who were married. This exploratory analysis was done for descriptive 359 purposes and did not test MAR assumptions about the missing data (Schafer & Graham, 2002). 360 As may be seen in Table 1, the majority of the participants identified as female (67.2%); 361 White, non-Hispanic (74.1%); having completed at least a 4-year college degree (60.1%); 362 married (65.2%); a full-time employee (62.6%); at least 40 years old (55.6%); and as residing in 363 a household with an annual income of at least \$70,000 (51.6%). Table 1 provides a comparison 364 of demographic characteristics, well-being self-efficacy scores, and health scores at T1 for 365 participants by randomization group. There were no statistically significant differences on the 366 proportions of demographic characteristics by randomization group. Similarly, there were no 367 statistically significant differences on the mean well-being self-efficacy scores or the mean 368 health scores at T1 (i.e., baseline) by randomization group. A majority (81.9%) of the 369 participants who were assigned to the FFW group were engaged with the FFW intervention. 370

371 Path Model

There was evidence for close to approximate fit of the path model to the observed data: $\chi^2_R(212) = 399, p < .001, RMSEA = .036 (.031, .042), SRMR = .031, CFI = .956, and TLI =$.929. There was evidence of acceptable levels of reliability for latent physical well-being selfefficacy at T1 (i.e., coefficient H = .78) and T2 (i.e., coefficient H = .77). Similarly, there was evidence of acceptable levels of reliability for latent psychological well-being self-efficacy at T1 (i.e., coefficient H = .80) and T2 (i.e., coefficient H = .78). Percentage of variance accounted for in latent well-being self-efficacy at T2 was 48.3% for latent physical well-being self-efficacy and

59.9% for latent psychological well-being self-efficacy. There was evidence of acceptable levels 379 of reliability for physical health status ($\alpha = .91$) and for mental health status ($\alpha = .83$) at T3. 380 Percentage of variance accounted for in health at T3 was 71.6% for physical health status and 381 382 60.5% for mental health status. The unstandardized estimates of the covariates (i.e., non-focal 383 parameters) for both physical health status and mental health status are available in Table 2, but these estimates are not discussed further due to spatial limitations. The unstandardized estimate 384 of each focal parameter from the path model by hypothesis is provided in Table 3 and these 385 estimates are discussed below. Figure 3 visually depicts key focal unstandardized parameter 386 387 estimates for Hypothesis 1 through Hypothesis 3. Hypothesis 1. The first hypothesis was that FFW would exert a positive direct effect on well-388 being self-efficacy. The adjusted mean difference on latent physical well-being self-efficacy at 389 T2 for the FFW group as compared to the UC group was both statistically non-significant and 390 negligible in size, $\hat{\beta}_1 = -0.04$, p = .549, d = -0.07. Conversely, the adjusted mean difference on 391

latent psychological well-being self-efficacy at T2 for the FFW group as compared to the UC group was both statistically significant and meaningful (though approximately small) in size, $\hat{\beta}_1$ = 0.14, p = .036, d = 0.26. In other words, FFW increased psychological well-being self-efficacy at T2, but failed to do so for physical well-being self-efficacy. Thus, only partial support was provided for hypothesis 1.

Hypothesis 2. The second hypothesis was that well-being self-efficacy would exert a positive direct effect on health. The path coefficient from latent physical well-being self-efficacy at T2 to physical health status at T3 was statistically significant, $\hat{\beta}_2 = 1.15$, p = .004. Similarly, the path coefficient from latent psychological well-being self-efficacy at T2 to mental health status at T3

also was statistically significant, $\hat{\beta}_2 = 3.13$, p < .001. In other words, both physical and 401 psychological well-being self-efficacy at T2 predicted improved physical and mental health 402 status at T3 respectively. Thus, full support was provided for hypothesis 2. 403 Hypothesis 3. Our third hypothesis was that FFW would exert a positive direct effect on health. 404 The adjusted mean difference on physical health status at T3 for the FFW group as compared to 405 the UC group was both statistically significant and meaningful (though approximately small) in 406 size, $\hat{\beta}_3 = 1.33$, p = .005, d = 0.24. Conversely, the adjusted mean difference on mental health 407 status at T3 for the FFW group as compared to the UC group was both statistically non-408 significant and negligible in size, $\hat{\beta}_3 = -0.22$, p = .694, d = -0.04. In other words, FFW was able 409 to improve physical health status directly but not mental health status. Thus, only partial support 410 was provided for hypothesis 3. 411 Hypothesis 4. The last hypothesis was FFW would exert a positive indirect effect on health 412 through well-being self-efficacy. The 95% CI for the product of path coefficients from FFW to 413 physical health status at T3 through latent physical well-being self-efficacy at T2 included 0.00, 414

415 $\hat{\beta}_4 = -0.05$, [-0.26, 0.10]. Conversely, the 95% CI for the product of path coefficients from FFW

416 to mental health status at T3 through latent psychological well-being self-efficacy at T2 did not

417 include 0.00, $\hat{\beta}_4 = 0.44$, [0.05, 0.94]. In other words, there was no evidence of a positive indirect

418 effect of FFW on physical health status through physical well-being self-efficacy. However,

there was evidence supporting a positive indirect effect of FFW on mental health status at 60

420 days after baseline through psychological well-being self-efficacy. Thus, only partial support

421 was provided for hypothesis 4.

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Λ	2	2
4	4	3

Discussion

The objective of the current study was to evaluate the effectiveness of the FFW online 424 intervention to increase physical and mental health status in adults with obesity in the USA. 425 Unlike an earlier clinical trial of FFW, this one was conducted in a relatively uncontrolled 426 setting. In general, results show that, compared to participants in the UC condition, those who 427 took part in the FFW intervention significantly improved their physical and mental health status. 428 Interestingly, the mechanisms through which these positive results were achieved were different 429 for physical and mental health. In the case of physical health, FFW exerted a direct effect; but in 430 the case of mental health, there was an indirect effect mediated through self-efficacy. More 431 precisely, the indirect effect was mediated by psychological well-being self-efficacy. We have 432 some ideas why FFW operated differently on physical and mental health in this trial. 433 To begin with, participants were specifically primed to focus mainly on a physical goal 434 for this clinical trial. In addition, to achieve better outcomes in the physical health domain, it is 435

important to take some direct action, such as eating more fruits and vegetables or walking more. 436 In contrast, to enhance mental health, cognitive reframing and a great deal of reflection is 437 required (Dacre Pool & Qualter, 2012). It is hard to improve mental health without engaging in 438 439 some cognitive processes, such as challenging erroneous assumptions about oneself or making an effort to cope with negative emotions (Norcross, 2012). These tasks may require a higher 440 level of self-efficacy beliefs than just walking 30 minutes a day, which is an obvious and 441 442 achievable task. Improving one's perceptions of self-worth, on the other hand, is a more nuanced and gradual process. It is one that requires self-compassion and a great deal of psychological 443 processing and insight. The very act of challenging one's assumptions both requires and 444 445 improves self-efficacy at the same time (Maddux, 2009).

In line with prior literature, our findings accentuate the importance of measuring self-446 efficacy in these types of interventions (Dacre Pool & Qualter, 2012; Duranso, 2018; Schmitt et 447 al., 2014; Stuifbergen et al., 2010). The useful role of self-efficacy in FFW and other preventive 448 interventions has been demonstrated in earlier studies (Myers, Prilleltensky, Hill, & Feltz, 2017). 449 The fact that FFW improved physical and mental health in people with obesity is 450 especially important, given that this is a population that experiences higher levels of risk. In line 451 with our second hypothesis, self-efficacy at 30 days led to positive outcomes in both domains of 452 health after 60 days. In a previous publication, it was also reported that FFW improved physical 453 activity self-efficacy in this group (Myers, McMahon, Prilleltensky, et al., 2020). Taken as a 454 whole, there is hope that improved self-efficacy, a key target of FFW, will indeed enhance the 455 well-being of people with weight problems. FFW seems to increase a person's sense of 456 competency and mastery. Indeed, the importance of self-efficacy to improve both physical and 457 mental health cannot be overstated. In a systematic review of the literature that examined 458 mediators for physical activity, Lewis and colleagues (2002) found that one of the most common 459 was self-efficacy. Therefore, we recommend that developers of future interventions for people 460 with obesity build into their program activities that enhance self-efficacy. 461

FFW is a methodic way to increase self-efficacy in participants by scaffolding their level of competence in the physical and psychological domains. Participants are presented with a variety of challenges that gradually develop their sense of mastery in these key aspects of wellness. The activities build competence in participants through a variety of means in line with Bandura's (1997) recommendations. People nurture their self-efficacy in FFW through enactive mastery experiences, vicarious experiences, verbal persuasion, and physiological and/or

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468 emotional states. Some of the challenges include video games, self-reflection exercises, and469 answering questions based on case studies where actors enact scenarios of competence.

470 Notably, this is the first time in which FFW outcomes are measured using the OptumTM

471 SF-36v2 Health Survey, which is a highly reliable and widely accepted tool (Ware, 2000; Ware

472 & Kosinski, 1996). In previous reports the main well-being outcome was the I COPPE scale

473 (Prilleltensky et al., 2015). The fact that we obtained positive results using another well-

established measure provides further evidence that FFW is indeed an effective health promotionprogram.

Thus far, FFW has been tried with a population of healthy adults and a population of 476 adults with obesity. In both randomized controlled trials there were positive results in improving 477 subjective well-being (Myers, Prilleltensky, Prilleltensky, et al., 2017), generating well-being 478 actions (Myers, Dietz, et al., 2018), enhancing general and specific self-efficacy (Myers, 479 Prilleltensky, Hill, & Feltz, 2017), and increasing physical activity (Myers, McMahon, et al., 480 2020). In this study we extend the results to enhanced physical and mental health status. In light 481 of the fact that FFW teaches people how to use the BET I CAN skills to improve well-being in 482 several domains of life, such as physical, psychological, interpersonal, and occupational, it is 483 484 worth considering its expansion to other populations.

The fact that FFW is scalable and accessible (<u>www.funforwellness.com</u>) overcomes many of the barriers from usual forms of health care, such as high-cost and lack of access. In addition, there are no negative side effects usually associated with many biologic interventions. FFW was conceptualized as a health promotion intervention. As such, we recommend its use in a variety of settings. For example, doctors can recommend it to patients and colleges to students. Similarly, it can be used by the military for soldiers and by corporations for their

employees. The personal and economic costs of obesity and mental distress on individuals and 491 society as a whole are just exorbitant (Mohney, 2018; WHO, 2018). It is imperative to develop 492 and test more interventions such as FFW that are easily accessible, interactive, and effective. 493 Although the results of the current study are encouraging, there are some important 494 limitations. The outcomes are based on self-report and we are working on a pilot to measure the 495 impact of FFW on physiological measures. Another limitation is the demographic profile of our 496 sample, which consisted mainly of individuals who identified as females (67.2%); White, non-497 Hispanic (74.1%); having completed at least a 4-year college degree (60.1%); married (65.2%); a 498 full-time employee (62.6%); at least 40-years old (55.6%); and as residing in a household with 499 an annual income of at least 70,000 (51.6%). This is a somewhat privileged group. In future 500 studies it would be important to evaluate FFW with less privileged populations. Future research 501 may also randomly assign different levels of access to BET I CAN challenges to better 502 understand issues of dose for the FFW intervention. Finally, we should be aware of the 503 limitations of interventions like this one that address mainly changes required within individuals. 504 To promote health and wellness for all, it is important to work also at the systemic level, with 505 policies addressing inequality and social determinants of health such as lack of universal health 506 507 care (Prilleltensky, 2005; Prilleltensky, 2012; Prilleltensky & Prilleltensky, 2006).

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Table 1

Demographic Characteristics, Well-Being Self-Efficacy (WBSE) Scores, and Health Scores at Time 1 for Participants by Randomization Group

Variable	Usual Care		Fun For Wellness	
Female	66.1%		68.5%	
Black	16.	1%	14.	2%
Hispanic	7.7	7%	6.9%	
Vocational or technical school	6.7	7%	7.6%	
Some college	18.	8%	18.8%	
Undergraduate degree	42.	3%	37.2%	
Graduate or professional degree	19.	8%	20.5%	
Living with partner	6.0)%	7.3%	
Married	66.	1%	64.2%	
Single	15.2%		13.9%	
Part-time employment	11.9%		9.4%	
Full-time employment	60.7%		64.4%	
Retired	9.2	2%	9.8%	
	M	SD	M	SD
Age in years	43.35	11.12	44.02	11.04
Income	71986	50426	76016	91859
Physical WBSE ($\alpha = .77$)	2.30	0.89	2.41	0.88
Psychological WBSE ($\alpha = .78$)	2.46	0.91	2.42	0.97
Physical health status ($\alpha = .89$)	48.01	9.49	48.49	9.02
Mental health status ($\alpha = .82$)	42.90	9.61	43.15	9.71

Note. The reference group (e.g., male) for each demographic variable (e.g., gender) and subgroups comprising less than 5% of observations are not reported for spatial reasons. Missing data ranged from 0% to 2.85% across all of the variables in this table.

Table 2

Unstandardized Estimate of the Covariates from the Path Model

	Outcome			
Predictor	Physical well-being self-efficacy at Time 2	Psychological well-being self-efficacy at Time 2	Physical health status at Time 3	Mental health status at Time 3
Female	0.07(.08)	-0.06(.07)	0.37(.52)	0.52(.60)
Black	0.15(.10)	0.04(.09)	1.15(.73)	-1.60(.88)
Hispanic	0.17(.13)	0.24(.14)	-0.71(1.07)	-2.43(.93)**
Vocational or technical school	-0.04(.16)	0.31(.14)*	-0.32(1.01)	1.11(1.61)
Some college	-0.09(.12)	0.10(.14)	-2.01(.88)*	-0.98(1.10)
Undergraduate degree	-0.11(.12)	-0.18(.13)	0.07(.83)	-0.74(1.02)
Graduate or professional degree	-0.05(.14)	0.02(.14)	-1.26(.95)	-2.40(1.13)*
Living with partner	-0.30(.16)	0.03(.18)	0.68(1.33)	-2.66(1.63)
Married	-0.14(.11)	0.33(.11)**	2.82(.84)***	-0.51(1.04)
Single	-0.34(.14)*	-0.01(.14)	0.80(1.02)	-0.98(1.21)
Part-time employment	0.06(.12)	0.19(.13)	2.07(1.04)*	-0.17(1.17)
Full-time employment	0.01(.11)	0.11(.12)	1.85(.83)*	0.06(1.02)
Retired	-0.34(.15)*	0.14(.16)	-0.73(1.14)	0.68(1.41)
Age in years	-0.003(.004)	-0.002(.004)	-0.08(.03)**	0.06(.04)
Income in thousand dollars	.000(.000)	-0.001(.000)*	-0.008(.002)***	0.009(.002)***
Physical well-being self-efficacy at Time 1	0.60(.06)***			
Psychological well-being self-efficacy at Time 1		0.60(.07)***		
Physical health status at Time 1	0.01(.04)		0.82(.03)***	
Mental health status at Time 1		0.02(.01)**		0.59(.05)***

Note. * p < .05, two-tailed. ** p < .01, two-tailed. *** p < .001, two-tailed.

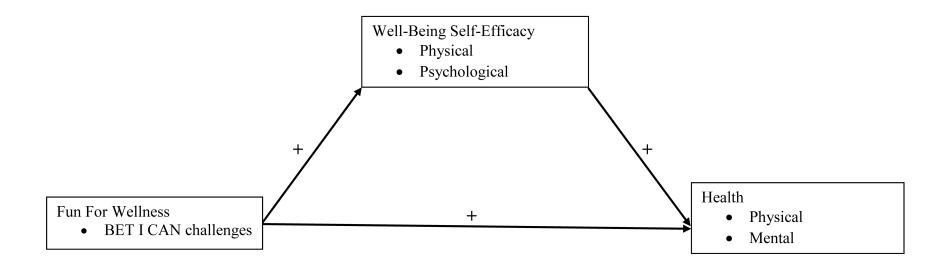
Table 3

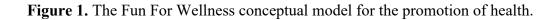
Unstandardized Estimate of each Focal Parameter from the Path Model by Hypothesis

Hypothesis 1: Fun For Wellness (FFW)	\rightarrow Well-Being S	elf-Efficacy		
Specific Path	$\beta_1(SE)$	[95% CI]	d	[95% CI]
$FFW \rightarrow Physical well-being self-efficacy at Time 2$	-0.04(0.07)	[-0.17, 0.09]	-0.07	[-0.22, 0.08]
$FFW \rightarrow Psychological well-being self-efficacy at Time 2$	0.14(0.07)*	[0.01, 0.27]	0.26	[0.11, 0.41]
Hypothesis 2: Well-Being Self	-Efficacy \rightarrow Hea	lth		
Specific Path	β ₂ (<i>SE</i>)	[95% CI]		
Physical well-being self-efficacy at Time $2 \rightarrow$ Physical health status at Time 3	1.15(0.40)**	[0.36, 1.94]	-	
Psychological well-being self-efficacy at Time $2 \rightarrow$ Mental health status at Time 3	3.13(0.58)***	[2.00, 4.26]		
Hypothesis 3: FFW \rightarrow Health				
Specific Path	$\beta_3(SE)$	[95% CI]	d	[95% CI]
$FFW \rightarrow Physical health status at Time 3$	1.33(0.48)**	[0.40, 2.27]	0.24	[0.09, 0.39]
$FFW \rightarrow Mental health status at Time 3$	-0.22(0.57)	[-1.33, 0.89]	-0.04	[-0.19, 0.12]
Hypothesis 4: FFW \rightarrow Well-Being Self-Efficacy \rightarrow Health				
Specific Path	β 4(<i>SE</i>)	[95% CI]		
FFW \rightarrow Physical well-being self-efficacy at Time 2 \rightarrow Physical health status at Time 3	-0.05(0.08)	[-0.26, 0.10]	-	
$FFW \rightarrow Psychological well-being self-efficacy at$ Time 2 \rightarrow Mental health status at Time 3	0.44(0.23)	[0.05, 0.94]†		

Note. d =Cohen's d; $\dagger =$ Bias corrected confidence interval did not include zero.

* p < .05, two-tailed. ** p < .01, two-tailed. *** p < .001, two-tailed.





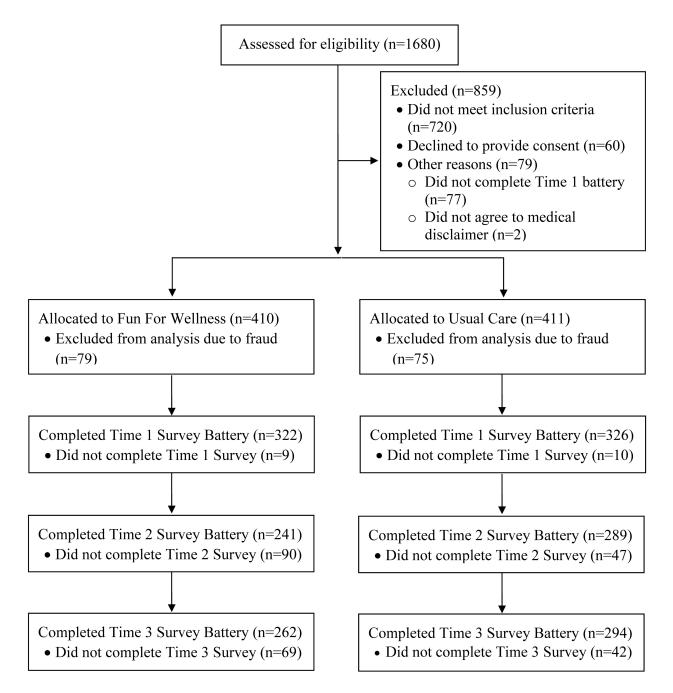


Figure 2. Participant flow from screening to randomization to retention over the three

measurement occasions for the health data.

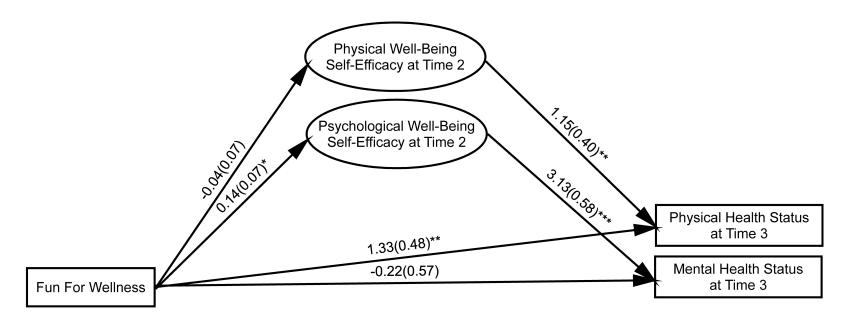


Figure 3. Key focal unstandardized parameter estimates from the path model for Hypothesis 1 through Hypothesis 3. Estimates for Hypothesis 4 are not directly provided because they are not parameter estimates per se but rather a function of existing parameter estimates. They are, however, listed at the bottom of Table 3. The 206 non-focal parameter estimates are not depicted to reduce clutter.