

Cell Phone Intervention for You (CITY): A Randomized, Controlled Trial of Behavioral Weight Loss Intervention for Young Adults Using Mobile Technology

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Objective: To determine the effect on weight of two mobile technology-based (mHealth) behavioral weight loss interventions in young adults.

Methods: Randomized, controlled comparative effectiveness trial in 18- to 35-year-olds with BMI ≥ 25 kg/m² (overweight/obese), with participants randomized to 24 months of mHealth intervention delivered by interactive smartphone application on a cell phone (CP); personal coaching enhanced by smartphone self-monitoring (PC); or Control.

Results: The 365 randomized participants had mean baseline BMI of 35 kg/m². Final weight was measured in 86% of participants. CP was not superior to Control at any measurement point. PC participants lost significantly more weight than Controls at 6 months (net effect -1.92 kg [CI $-3.17, -0.67$], $P = 0.003$), but not at 12 and 24 months.

Conclusions: Despite high intervention engagement and study retention, the inclusion of behavioral principles and tools in both interventions, and weight loss in all treatment groups, CP did not lead to weight loss, and PC did not lead to sustained weight loss relative to Control. Although mHealth solutions offer broad dissemination and scalability, the CITY results sound a cautionary note concerning intervention delivery by mobile applications. Effective intervention may require the efficiency of mobile technology, the social support and human interaction of personal coaching, and an adaptive approach to intervention design.

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Introduction

Obesity is present in 35% of young adults (defined as age 18-35 years) in the US (1) and deserves attention: Weight gain is most rapid during these years (2,3); increasing body mass index (BMI) in young adulthood increases the risk of developing metabolic

syndrome over the subsequent 15 years almost 20-fold (4); and weight gain in early adulthood is also associated with increased coronary calcification in middle age (5), forecasting future cardiovascular disease (CVD) events. These data suggest the need for effective and sustainable weight control strategies early in adult life (6).

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Effective behavioral weight loss strategies involve regular personal contact with a trained interventionist using behavioral techniques such as self-monitoring and goal setting (6). Evidence-based obesity treatment recommendations endorse high-intensity intervention: ≥ 14 in-person interventionist sessions over 6 months (6). However, the optimal behavioral “dose” is unclear (7), and a smaller effect with lower intensity intervention might be offset by the potential for increased scalability. In addition, trials testing comprehensive behavioral approaches have primarily included middle-aged adults and suggest that intervention is more effective as age increases (8,9). Thus the potential of personal coaching for weight loss in a younger population is unknown.

Similarly, commercial mobile technology mHealth applications (“apps”) are widely downloaded for weight loss but have not been rigorously tested for efficacy or effectiveness. Behavior change techniques known to produce clinically meaningful weight loss are often absent (10,11), calling into question whether apps can have the desired effect (12,13).

Because of the potential for scalability and wide dissemination, we sought to determine the weight loss potential of mobile technology on its own. In order to improve the efficiency of behavior change methods known to be effective, we tested a low-intensity personal coaching intervention enhanced by mobile technology. The Cell Phone Intervention for You (CITY) study was a three-arm randomized trial comparing the effect on weight over 24 months of behavioral intervention that was delivered almost entirely via a smartphone app of our design (CP) or behavioral intervention delivered through personal coaching enhanced by self-monitoring via smartphone (PC), each compared to Control. We hypothesized that CP and PC would each be superior to Control. We made no *a priori* hypothesis about CP relative to PC.

Methods

The CITY study was one of seven trials in the Early Adult Reduction of weight through Lifestyle Intervention (EARLY) consortium, sponsored by NHLBI (1U01HL096720). Each EARLY trial was conducted independently. However, in order to facilitate future comparison, the EARLY trials had common eligibility criteria, measurement methods, and primary outcome (14). The design of CITY is reported elsewhere (15).

Study population

CITY was approved by the Duke Institutional Review Board and an NHLBI-appointed Protocol Review Committee/Data and Safety Monitoring Board (DSMB). Enrollment occurred between December 2010 and February 2012. Individuals were eligible if they were aged 18–35 years, had overweight or obesity ($\text{BMI} \geq 25 \text{ kg/m}^2$), and used a mobile telephone. For logistical reasons, participants were required to receive service from either Verizon or AT&T.

Individuals were excluded if they were taking weight loss medications or corticosteroids, had weight loss surgery, weighed more than 440 lbs (the limit of study scales), or had any condition deemed unsafe for the study. Recruitment occurred primarily by advertising and mass mailings.

Pre-screening assessment occurred by participants’ choice of telephone, interactive voice response (IVR), short message service (SMS), or online survey. Participants were further screened by telephone followed by a face-to-face visit, during which all participants provided written informed consent.

Randomization occurred at a separate face-to-face visit within 10 weeks of screening, at which baseline weight was obtained. Randomization was stratified by gender and BMI (overweight [$\text{BMI} \geq 25$ and $< 30 \text{ kg/m}^2$] vs. obese [$\text{BMI} \geq 30 \text{ kg/m}^2$]) with equal allocation to each treatment group. Intervention lasted 24 months, with data collection at 6, 12, and 24 months post-randomization.

Outcomes

The primary outcome was weight change in kilograms (kg) at 24 months. Secondary outcomes included weight changes at 6 and 12 months, percent change in weight at each time point, and weight changes in subgroups defined by self-identified race, sex, and age. Other pre-specified outcomes include change in dietary pattern and physical activity (PA) (15).

Interventions

Both the cell phone (CP) and personal coaching (PC) interventions were designed by our research team, based on social cognitive theory (16) and the transtheoretical model (17). Both interventions used techniques of behavioral self-management (18) and motivational enhancement (19). Targeted goals and behaviors included moderate calorie restriction, healthy dietary pattern (based on the Dietary Approaches to Stop Hypertension [DASH] dietary pattern) (20), ≥ 180 min/week of moderate PA, limited alcohol intake, and frequent self-monitoring of weight, diet, and PA (6). Both interventions were designed with input from the target population obtained through focus groups that were conducted in the year before the trial began (21).

The major difference between CP and PC was the source of intervention delivery and the use of the smartphone. In CP, the smartphone was used for both intervention delivery and self-monitoring. Specifically, the intervention was delivered exclusively through an investigator-designed smartphone app which included goal setting, challenge games, and social support through a “buddy system” that allowed exchange of pre-determined messages to a randomly assigned buddy participant. Self-management behaviors for CP were regularly and frequently prompted by the app according to a protocol-driven schedule; participants did not have a choice in the timing or frequency of prompts. Tailoring within the CP intervention occurred mainly via setting personal goals. Self-monitoring by smartphone was achieved by tracking weight, dietary intake, and physical activity, with frequent prompts to self-monitor and feedback on the results.

In contrast, the PC intervention was delivered primarily by an interventionist during six weekly group sessions followed by monthly phone contacts. Intervention elements such as goal setting, challenges, and social support were delivered through these personal coaching interactions, with extensive tailoring during the conversations with the interventionist. The smartphone was used exclusively for self-monitoring, with tracking of weight, dietary intake, and physical activity initiated by the participant (i.e., without smartphone prompts), transmitted to the interventionist, and incorporated by the interventionist into the coaching sessions. The PC interventionists were dietitians trained in Motivational

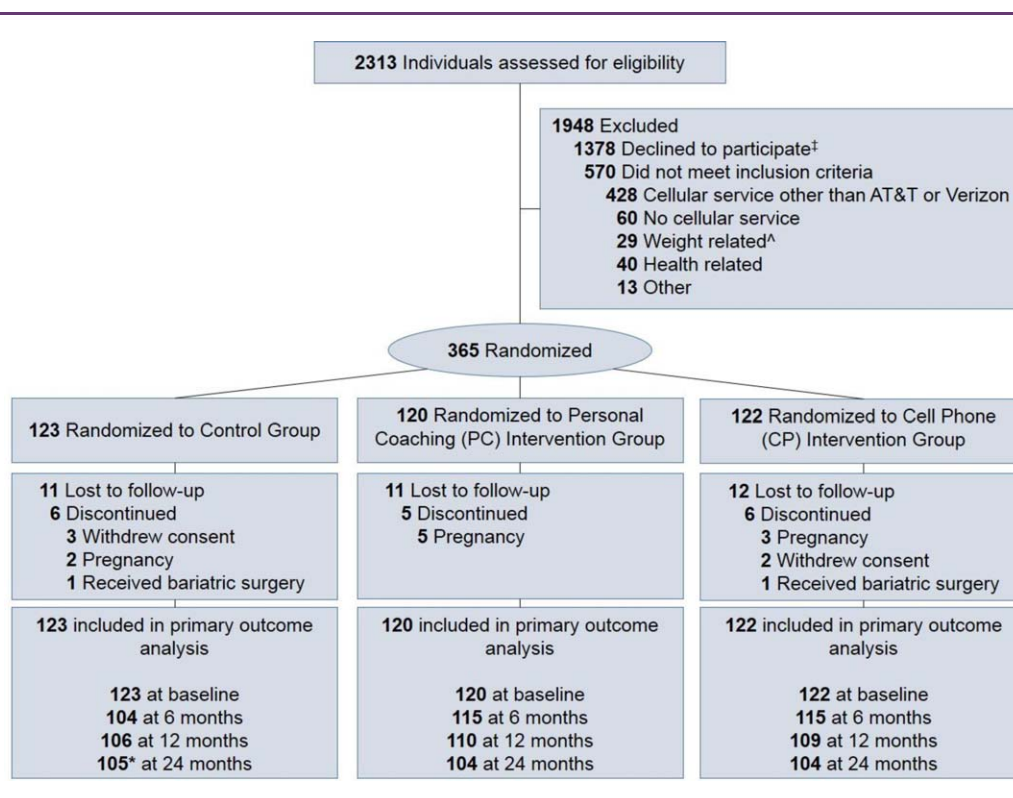


Figure 1 CONSORT diagram. *1 additional Control participant did not have 24-month weight but contributed data for other outcomes. ^Includes: weight loss surgery, program, intervention study ($n = 20$); BMI < 25 kg/m² ($n = 7$); >15 lbs weight loss in last 3 months ($n = 2$). †Participants were eligible at time in screening process when they declined.

Interviewing. Fidelity to the intervention protocol was monitored by the intervention director (P-HL) during regular observation of the group sessions and review of audiotaped monthly calls.

In both CP and PC, participants received an Android smart phone, and their personal phone number was transferred to the CITY phone. Participants were expected to use the CITY phone as their sole personal phone. Because text and data service were required for both interventions, participants were reimbursed for this portion of their phone bill. Participants were also provided a Bluetooth-enabled scale (Tanita HD-351BT) for weight self-monitoring, which automatically transmitted weight through their smartphone to the study database.

Participants randomized to the Control group were given three hand-outs on healthy eating and physical activity from the Eat Smart Move More NC program (<http://www.eatsmartmovemorenc.com/>) but otherwise received no intervention and were not asked to self-monitor. Use of these materials was not monitored.

Measurements

Study measurements were collected on-site in all randomized participants at baseline and at 6, 12, and 24 months by trained, certified study personnel.

Weight was measured in duplicate to the nearest 0.1 lb, with the participant in light indoor clothes without shoes, using a high-quality calibrated digital scale.

Height was measured in duplicate to the nearest 0.1 cm, with the participant shoeless using a wall-mounted stadiometer.

BMI was calculated as weight [kg]/height [m]².

Waist circumference was measured in duplicate to the nearest 0.1 cm, at the level of the upper iliac crest at the end of a normal exhalation.

Dietary intake was assessed by duplicate self-administered 24-h dietary recall (22). Data are summarized as the Healthy Eating Index (HEI), reflecting adherence to DASH (23) and future health outcomes (24).

Each of the above duplicate measures was averaged at each visit.

Physical activity (PA) in kilocalories per week was assessed by the Paffenbarger questionnaire (25).

Statistical analysis

The primary analysis was based on intention-to-treat principles. The outcome for the two main study hypotheses (CP vs. Control and PC vs. Control) was absolute weight change in kilograms from baseline to 24 months. A constrained longitudinal data analysis model (cLDA) was used to estimate changes in absolute weight over time and test the primary hypotheses (26). The variables in the model included dichotomous stratification factors (BMI ≥ 25 to <30 vs. BMI ≥ 30 kg/m², and male vs. female), a time effect, and the

TABLE 1 Baseline characteristics

	Overall	Control	CP	PC
Total, no.	365	123	122	120
Age (years), mean (SD)	29.4 (4.3)	29.6 (4.3)	29.2 (4.2)	29.4 (4.3)
Female, no. (%)	254 (69.6)	85 (69.1)	84 (68.9)	85 (70.8)
Race category, no. (%)				
White	205 (56.2)	72 (58.5)	68 (55.7)	65 (54.2)
Black	132 (36.2)	42 (34.1)	42 (34.4)	48 (40.0)
Other	28 (7.7)	9 (7.3)	12 (9.8)	7 (5.8)
Hispanic ethnicity, no. (%)	21 (5.8)	5 (4.1)	9 (7.4)	7 (5.8)
Education level, no. (%)				
Some college or less	130 (35.6)	40 (32.5)	39 (32.0)	51 (42.5)
College degree or higher	235 (64.4)	83 (67.5)	83 (68.0)	69 (57.5)
Personal income category, no. (%)				
<24,999	121 (34.0)	43 (35.5)	38 (31.9)	40 (34.5)
25,000-49,999	150 (42.1)	50 (41.3)	55 (46.2)	45 (38.8)
≥50,000	85 (23.9)	28 (23.1)	26 (21.8)	31 (26.7)
In committed relationship, no. (%)	217 (59.8)	72 (59.0)	72 (59.0)	73 (61.3)
Student, no. (%)	124 (34.3)	42 (34.1)	43 (35.8)	39 (32.8)
Working, no. (%)	308 (85.1)	96 (79.3)	107 (88.4)	105 (87.5)
Weight in kg, mean (SD)	101.0 (23.7)	101.3 (22.6)	102.4 (25.2)	99.3 (23.4)
Body mass index (kg/m ²), mean (SD) [min, max]	35.2 (7.8) [24.9, 62.4]	35.1 (7.5) [25.3, 61.6]	35.7 (8.2) [25.1, 62.4]	34.9 (7.5) [24.9, 58.9]
BMI category, no. (%)				
Overweight, 25-29.99 kg/m ²	109 (29.9)	38 (30.9)	36 (29.5)	35 (29.2)
Class I obese, 30-34.99 kg/m ²	110 (30.1)	33 (26.8)	34 (27.9)	43 (35.8)
Class II obese, 35-39.99 kg/m ²	52 (14.2)	19 (15.4)	16 (13.1)	17 (14.2)
Class III obese, 40+ kg/m ²	94 (25.8)	33 (26.8)	36 (29.5)	25 (20.8)
Waist circumference in cm, mean (SD)				
Males	111.7 (16.3)	109.8 (14.6)	113.8 (17.9)	111.5 (16.4)
Females	108.2 (16.8)	107.9 (15.7)	109.3 (18.4)	107.4 (16.4)
Hypertension ^a , no. (%)	59 (16.2)	20 (16.3)	20 (16.4)	19 (15.8)
HEI ^b Score, mean (SD)	51.0 (4.1)	50.7 (4.4)	51.6 (4.2)	50.8 (3.6)
Leisure-time physical activity (kcal/week), mean (SD) ^c	879.7 (1,134.2)	865.9 (1,133.9)	1,009.3 (1,346.4)	756.0 (846.1)

There were no significant differences among treatment groups

CP, cell phone intervention; PC, personal coaching intervention; SD, standard deviation; BMI, body mass index, calculated as weight in kilograms divided by height in meters squared; HEI, Healthy Eating Index.

Missing values: income:9; relationship status:2; student:3; work:3; hei:32; physical activity:18.

^aHypertension defined as SBP > 140 or DBP > 90 mmHg or taking BP meds.

^bHealthy Eating Index (HEI-2005) (<http://riskfactor.cancer.gov/tools/instruments/asa24/>).

^cReports of >10 flights climbed per day were considered implausible and excluded from analysis.

treatment-by-time interaction. The Holm sequential testing procedure (27) maintained an overall type I error rate of 0.05 for the analysis of the primary hypotheses.

Secondary study outcomes were analyzed similarly. Models evaluating effects in pre-specified race, sex, and age subgroups as well as *post hoc* subgroups based on baseline BMI category, income, and education also include the subgroup variable and its interaction with treatment, with a nominal type I error rate of 0.05.

Missing data was addressed in our primary statistical modeling approach by maximum likelihood methods (28). Sensitivity analyses

included multiple imputation and a “benchmark” not missing at random (NMAR) analysis that assumes that CP and PC missing values are similar to those of non-missing Controls.

Power and sample size calculations were based on estimates from previous behavioral weight loss trials (29,30): estimated common standard deviation of weight of 16.6 kg at baseline, 0.8 correlation between weight measurements within individuals, and 25% attrition; and weight gain of 1.5 kg/year in Controls (3). With these assumptions, a projected sample size of 120 participants per group ($N = 360$) provided greater than 80% power at alpha 0.025 to detect a difference in weight change of 5 kg.

TABLE 2 Intervention adherence

	0-6 months	7-12 months	13-24 months
CP, N (% of randomized)	121 (99)	115 (94)	105 (86)
Self-weighing, mean times/week (SD)	4.0 (1.7)	3.3 (1.9)	2.1 (1.7)
Number of interactions ^a with CITY app, mean per person per day (SD)	4.6 (3.0)	1.5 (1.4)	0.7 (0.7)
PC, N (% of randomized)	115 (96)	113 (94)	108 (90)
Self-weighing, mean times/week (SD)	2.2 (1.6)	1.3 (1.4)	1.0 (1.2)
Number of interactions ^a with CITY app, mean per person per day (SD)	1.8 (1.5)	0.8 (1.1)	0.4 (0.6)
Percent of contacts completed ^b (SD)	93.0 (16.4)	92.3 (20.8)	87.8 (21.2)

CP, cell phone intervention; PC, personal coaching intervention; SD, standard deviation.

^aInteractions include any usage of the CITY app except self-weighing. Total number of app components tracked in the CP and PC intervention was 31 and 24, respectively.

^b0- to 6-month data includes completion percentage for six weekly group sessions.

Results

A total of 365 individuals were randomized. Figure 1 shows the flow of participants through the study. Weight was obtained at 24 months in 86%. (Those without 24-month data reported slightly higher income and perceived stress but were otherwise similar to the overall randomized population.)

Study population (Table 1). At entry, mean age was 29.4 years, 69.6% were women, 43.9% were non-White race (36.2% of total were Black), and 5.8% were Hispanic ethnicity. The majority were college-educated and employed. Mean baseline BMI was 35.2 kg/m². One-fourth of study participants were overweight (BMI ≥25 to <30 kg/m²); one-fourth had class III obesity (BMI ≥40 kg/m²).

Intervention adherence (Table 2). The CP group self-weighed an average of 4.0 times/week for the first 6 months and continued at 2.1 times/week during months 13 through 24. CP participants interacted with the study app in other ways an average of 4.6 times/day in the first 6 months and 0.7 times/day in the final year. The PC group self-weighed an average of 2.2 times/week in the first 6 months and 1.0 times/week in the final year of intervention. Excluding weighing, the PC group interacted with the study app an average of 1.8 times/day in the first 6 months and 0.4 times/day in the final year. In addition, over 90% completed all expected coaching contacts in the first 6 months and more than 87% of monthly calls from months 13 through 24.

Weight loss. The primary outcome is depicted in Figure 2. CP participants lost the least weight at all measurement points (−0.87, −1.48, and −0.99 kg at 6, 12, and 24 months, respectively), and these values were not significantly different from Control (−1.14, −2.25, and −1.44 kg, respectively). PC had the greatest mean weight loss (−3.07, −3.58, and −2.45 kg at 6, 12, and 24 months, respectively), which was significantly greater than Control at 6 months (net effect −1.92 kg [CI −3.17 to −0.67], *P* = 0.003) and greater than CP at 6 months (net effect −2.19 kg [CI −3.42 to −0.97], *P* < 0.001) and 12 months (net effect −2.10 kg [CI −3.94 to −0.27], *P* = 0.025). There were no significant differences in mean weight loss at 24 months among the treatment groups. Sensi-

tivity analyses described above yielded consistent results. In addition, excluding two extreme outliers (weight loss of 41.2 kg and gain of 31.8 kg) yielded similar results. All findings were numerically similar when expressed as percent weight lost (see Supporting Information Figure 1).

Because commercial apps for weight loss were ubiquitous during the study, at the end of the final data collection visit, we administered a retrospective questionnaire about app usage. Use of at least one commercially available weight loss app during the study was reported in 30% of CP, 50% of PC, and 54% of Control.

Current guidelines define 3-5% weight loss as clinically meaningful, associated with significant health benefits (6). Weight loss of at least 5% at 24 months occurred in 25.5%, 27.5%, and 22.0% of CP, PC, and Control, respectively; these differences were not statistically significant.

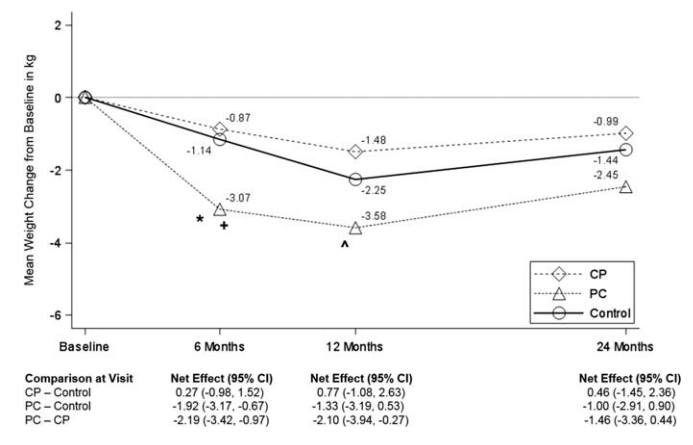
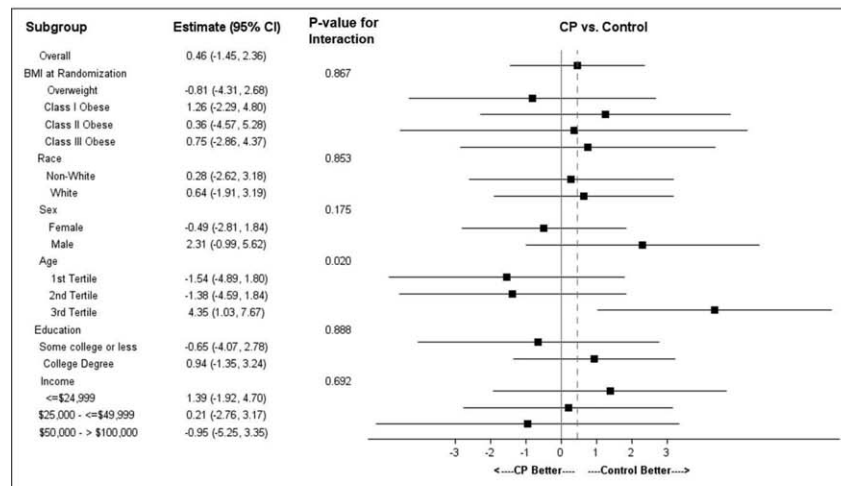
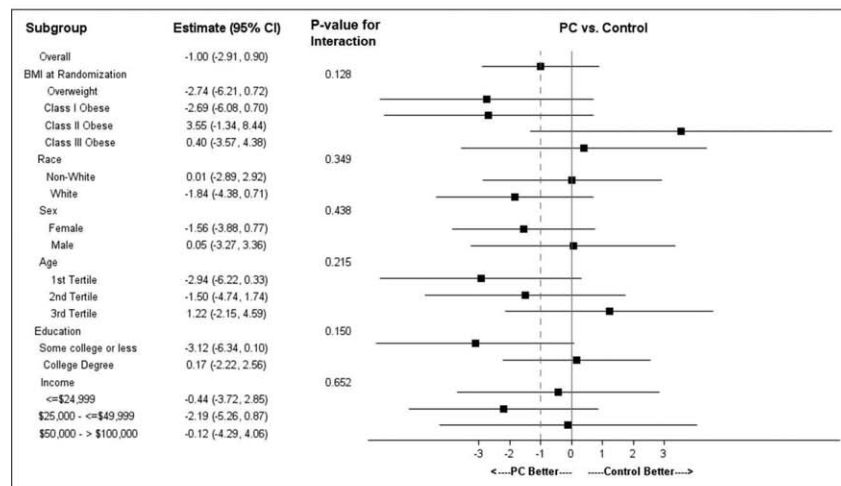


Figure 2 Effect of interventions on weight change (in kilograms), based on linear mixed model analyses. Abbreviations: CP, cell phone intervention; PC, personal coaching intervention. **P*-value = 0.003 for the comparison between PC and Control at 6 months. +*P*-value < 0.001 for the comparison between PC and CP at 6 months. ^*P*-value = 0.025 for the comparison between PC and CP at 12 months.

Panel A. CP vs Control



Panel B. PC vs Control.



Panel C. PC vs CP.

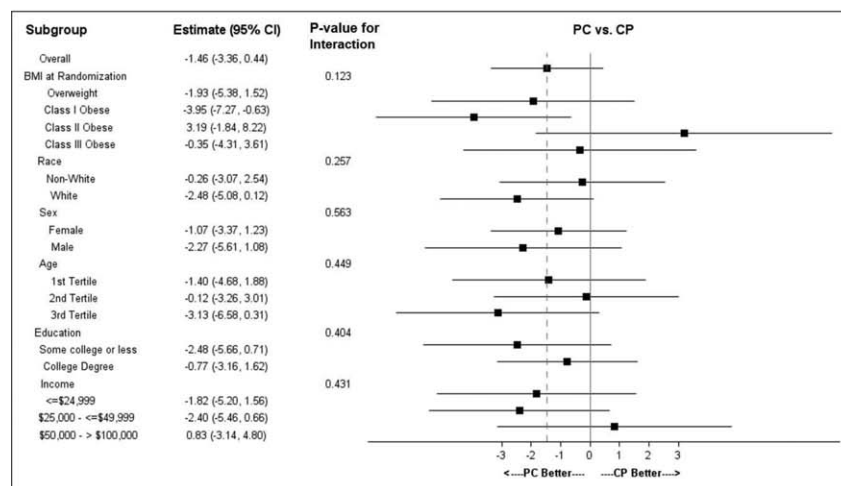


Figure 3 Subgroup analysis. Forest plots for pre-specified subgroups: age, sex, race; and *post hoc* subgroup: BMI category, education category, and income category. (A) CP vs. Control; (B) PC vs. Control; (C) CP vs. PC.

Subgroup effects (Figure 3). Comparisons of subgroups defined by baseline BMI category (overweight or obese class I, II, or III), race, sex, income, or education showed no difference in intervention effect by subgroup stratum. A differential intervention effect was observed between CP and Control participants across age tertiles, with the oldest participants losing the least weight as compared to younger participants. A similar but less pronounced age effect was observed between PC and Control.

Other effects. Adverse events did not differ among treatment groups, and no serious adverse events were considered to be study-related. HEI score at 24 months in CP was reduced relative to Control (-1.93 points [CI -3.75 to -0.11], $P = 0.039$); there were no other significant effects of either CP or PC on HEI or PA (see Supporting Information Figures 2 and 3).

Discussion

CITY is the largest and longest comparative effectiveness trial to investigate theory-based behavioral weight loss interventions that may be suitable for widespread dissemination and implementation. We found that, relative to Control, neither a mobile app alone nor personal coaching with mobile self-monitoring resulted in statistically significant weight loss after 24 months.

We designed and tested a smartphone intervention (CP) based on expectations that mHealth modalities can be particularly effective and scalable in young adults (31). But this behavioral intervention did not lead to significant weight loss relative to Control at any trial time point. Commercial apps intended to promote healthy lifestyle and weight loss are ubiquitous (10). However, behavior change principles are generally absent in these commercial products (10,11), and trials have shown no effect on weight (13) or dietary pattern (12). Lack of effect in trials using commercial apps may reflect lack of sustained engagement: only 39% of commercial apps are used more than 10 times before they are abandoned (32). Although CITY engagement may not have been sufficient, CP participants did continue to use the app an average of twice weekly (0.3 times/day) for 2 years.

It is possible that CITY did not have a sufficiently compelling or individually tailored app design (33). Our attempt to adhere to randomized trial conventions by testing exactly the same intervention in each participant made it impossible to adapt the app rapidly and iteratively in response to participant behavior and need. Indeed, future trials may need to consider “rapid, responsive, relevant (R3) design” (34) in which rapid assessment of usage and outcome allows for responsive design changes that keep the app relevant to users.

CP also may have been ineffective because it involved no human intervention contact. In contrast, PC was based on previous trials that incorporated face-to-face or phone contact frequently over a sustained period of time (6,29). Current obesity treatment guidelines recognize the need to “evaluate optimal frequency (and duration) of contact” [in order to focus] on improvements in efficiency and efficacy, [and to optimize] delivery and dissemination” (6). Consistent with this need, we attempted to increase the efficiency of the personal coaching approach by reducing the required face-to-face time

from at least 14 weekly sessions (6) to 6, followed by monthly phone contact. PC led to significant weight loss relative to Control at 6 months and relative to CP at 6 and 12 months, but the effect size was generally smaller than in studies with more in-person sessions (in older adults) (6,35,36). Thus it is possible that the dose or intensity was insufficient for sustained effect or that this intervention approach is less effective in younger than older adults (8,9). PC also differed from other personal coaching interventions in its reliance on a mobile app for self-monitoring, a feature that may enhance the effect of coaching (31). Ongoing additional analysis of detailed phone data for both CP and PC will allow us to identify usage patterns or other factors associated with weight loss.

Further research is needed to determine whether increasing both coaching contacts and mobile elements (essentially combining PC and CP) and/or more personal tailoring will increase and/or prolong weight loss.

The lack of efficacy at 24 months of both CITY interventions to some extent may be related to the behavior of the Control group, which experienced a somewhat better-than-expected outcome. Based on observational data (3), we expected the Control group to gain 1.5 kg/year (3), and in most similar trials, weight loss in the Control group is negligible (6). Yet after 24 months, average weight was reduced in Control participants, and 22% of them lost at least 5%. Weight loss in control participants is not unusual: Participants may enroll with high motivation that was enhanced by randomization to the Control group, and they may have employed other weight loss strategies. In fact, 54% of Control participants used commercial weight loss apps. However, there was no evidence that the use of commercial apps was associated with greater weight loss: the observed mean weight change from baseline to 24 months within the Control group was -1.2 kg (standard deviation [SD] 7.1) for users and -1.8 kg (SD 8.0) kg for non-users.

Characteristics of our study population may have contributed to the lack of sustained effect. The mean BMI was 35 kg/m^2 , and 25% had class III obesity, suggesting that CITY participants were not on the trajectory of weight gain but in fact had well-established obesity, and many had severe obesity. However, severe obesity is not necessarily an obstacle to behavioral weight loss (37), and in *post hoc analysis*, baseline BMI category did not modify intervention effect (Figure 3). In addition, CITY enrolled 36% African Americans, of whom most were Black women, a group that often experiences less weight loss than other trial participants (38,39). However, subgroup analysis did not suggest differential treatment effects by race. Similarly, there were no differences in treatment effects in subgroups defined (*post hoc*) by education or income (Figure 3). Overall, we noted marked heterogeneity in response (range of observed weight change -41.2 kg to $+31.8$ kg). These findings suggest the need to develop an intervention that is tailored to the individual.

Conclusion

In summary, although conclusions can be drawn only about the specific app tested, the CITY trial sounds a cautionary note concerning intervention delivery by mobile applications alone. Effective weight loss intervention for young adults that can be implemented efficiently and broadly may require the scalability of mobile technology, the

social support and human interaction of personal coaching, adaptive intervention design, and more personally tailored approaches. **O**

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Study participants

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Study data were collected and managed using Research Electronic Data Capture (REDCap) electronic data capture tools hosted at Duke University. REDCap is a secure, web-based application designed to support data capture for research studies, providing: (1) an intuitive interface for validated data entry; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common

statistical packages; and (4) procedures for importing data from external sources.

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References

1. Flegal KM, Carroll MD, Kit BK, Ogden CL. Prevalence of obesity and trends in the distribution of body mass index among US adults, 1999-2010. *JAMA* 2012;307:491-497.
2. Burke GL, Bild DE, Hilner JE, Folsom AR, Wagenknecht LE, Sidney S. Differences in weight gain in relation to race, gender, age and education in young adults: the CARDIA Study. *Coronary Artery Risk Development in Young Adults. Ethn Health* 1996;1:327-335.
3. Lewis CE, Jacobs DR Jr, McCreath H, et al. Weight gain continues in the 1990s: 10-year trends in weight and overweight from the CARDIA study. *Coronary Artery Risk Development in Young Adults. Am J Epidemiol* 2000;151:1172-1181.
4. Lloyd-Jones DM, Liu K, Colangelo LA, et al. Consistently stable or decreased body mass index in young adulthood and longitudinal changes in metabolic syndrome components: the Coronary Artery Risk Development in Young Adults Study. *Circulation* 2007;115:1004-1011.
5. Loria CM, Liu K, Lewis CE, et al. Early adult risk factor levels and subsequent coronary artery calcification: the CARDIA Study. *J Am Coll Cardiol* 2007;49:2013-2020.
6. Jensen MD, Ryan DH, Donato KA, et al. Guidelines (2013) for managing overweight and obesity in adults. *Obesity* 2014;22(S2):S1-S410.
7. Voils CI, King HA, Maciejewski ML, Allen KD, Yancy WS Jr, Shaffer JA. Approaches for informing optimal dose of behavioral interventions. *Ann Behav Med* 2014;48:392-401.
8. Svetkey LP, Clark JM, Funk K, et al. Greater weight loss with increasing age in the weight loss maintenance trial. *Obesity (Silver Spring)* 2014;22:39-44.
9. Wadden TA, Neiberg RH, Wing RR, et al. Four-year weight losses in the Look AHEAD study: factors associated with long-term success. *Obesity (Silver Spring)* 2011;19:1987-1998.
10. Pagoto S, Schneider K, Jovic M, DeBiaise M, Mann D. Evidence-based strategies in weight-loss mobile apps. *Am J Prev Med* 2013;45:576-582.
11. Breton ER, Fuemmeler BF, Abrams LC. Weight loss—there is an app for that! But does it adhere to evidence-informed practices? *Transl Behav Med* 2011;1:523-529.
12. Wharton CM, Johnston CS, Cunningham BK, Sterner D. Dietary self-monitoring, but not dietary quality, improves with use of smartphone app technology in an 8-week weight loss trial. *J Nutr Educ Behav* 2014;46:440-444.
13. Laing BY, Mangione CM, Tseng CH, et al. Effectiveness of a smartphone application for weight loss compared with usual care in overweight primary care patients: a randomized, controlled trial. *Ann Intern Med* 2014;161:S5-S12.
14. Lytle LA, Svetkey LP, Patrick K, et al. The EARLY trials: a consortium of studies targeting weight control in young adults. *Transl Behav Med* 2014;4:304-313.
15. Batch BC, Tyson C, Bagwell J, et al. Weight loss intervention for young adults using mobile technology: Design and rationale of a randomized controlled trial—Cell phone Intervention for You (CITY). *Contemp Clin Trials*, 2014;37:333-41.
16. Bandura A. *Social Foundations of Thought and Action: A Social Cognitive Theory*. Englewood Cliffs, NJ: Prentice Hall; 1986.
17. Prochaska JO, Velicer WF, Rossi JS, et al. Stages of change and decisional balance for 12 problem behaviors. *Health Psychol* 1994;13:39-46.
18. Watson DT. *Self-Directed Behavior: Self-Modification for Personal Adjustment*, 5th ed. Pacific Grove, CA: Brooks/Cole; 1989.
19. Miller WR, Rollnick S. *Motivational Interviewing: Preparing People for Change*, 2nd ed. Guilford Press, New York; 2002.
20. Appel LJ, Moore TJ, Obarzanek E, et al. A clinical trial of the effects of dietary patterns on blood pressure. DASH Collaborative Research Group. *N Engl J Med* 1997;336:1117-1124.
21. Corsino L, Lin PH, Batch BC, et al. Recruiting young adults into a weight loss trial: report of protocol development and recruitment results. *Contemp Clin Trials* 2013;35:1-7.
22. Automated Self-administered 24-hour Dietary Recall (ASA24). Available at: <http://riskfactor.cancer.gov/tools/instruments/asa24/>, accessed on February 9, 2010.
23. de Koning L, Chiuve SE, Fung TT, Willett WC, Rimm EB, Hu FB. Diet-quality scores and the risk of type 2 diabetes in men. *Diabetes Care* 2011;34:1150-1156.
24. Fung TT, Chiuve SE, McCullough ML, Rexrode KM, Logroscino G, Hu FB. Adherence to a DASH-style diet and risk of coronary heart disease and stroke in women. *Arch Intern Med* 2008;168:713-720.
25. Paffenbarger RS Jr, Hyde RT, Wing AL, Hsieh CC. Physical activity, all-cause mortality, and longevity of college alumni. *N Engl J Med* 1986;314:605-613.
26. Liu GF, Lu K, et al. Should baseline be a covariate or dependent variable in analyses of change from baseline in clinical trials? *Stat Med* 2009;28:2509-2530.
27. Proschan MA, Waclawiw MA. Practical guidelines for multiplicity adjustment in clinical trials. *Control Clin Trials* 2000;21:527-539.

28. Little RJ, D'Agostino R, Cohen ML, et al. The prevention and treatment of missing data in clinical trials. *N Engl J Med* 2012;367:1355-1360.
29. Svetkey LP, Stevens VJ, Brantley PJ, et al. Comparison of strategies for sustaining weight loss: the weight loss maintenance randomized controlled trial. *JAMA* 2008; 299:1139-1148.
30. The effects of nonpharmacologic interventions on blood pressure of persons with high normal levels. Results of the Trials of Hypertension Prevention, Phase I. *JAMA* 1992;267:1213-1220.
31. Spring B, Duncan JM, Janke EA, et al. Integrating technology into standard weight loss treatment: a randomized controlled trial. *JAMA Intern Med* 2013;173:105-111.
32. Available at: <http://info.localytics.com/blog/app-retention-improves>, accessed on January 10, 2015.
33. Christian B. The A/B test: inside the technology that's changing the rules of business. *Wired* April 25, 2012.
34. Riley WT, Glasgow RE, Etheredge L, Abernethy AP. Rapid, responsive, relevant (R3) research: a call for a rapid learning health research enterprise. *Clin Transl Med* 2013;2:10.
35. Appel LJ, Clark JM, Yeh HC, et al. Comparative effectiveness of weight-loss interventions in clinical practice. *N Engl J Med* 2011;365:1959-1968.
36. Wadden TA, Volger S, Sarwer DB, et al. A two-year randomized trial of obesity treatment in primary care practice. *N Engl J Med* 2011;365:1969-1979.
37. Goodpaster BH, Delany JP, Otto AD, et al. Effects of diet and physical activity interventions on weight loss and cardiometabolic risk factors in severely obese adults: a randomized trial. *JAMA* 2010;304:1795-1802.
38. Wingo BC, Carson TL, Ard J. Differences in weight loss and health outcomes among African Americans and whites in multicentre trials. *Obes Rev* 2014;15:46-61.
39. Wadden TA, West DS, Neiberg RH, et al. One-year weight losses in the Look AHEAD study: factors associated with success. *Obesity (Silver Spring)* 2009;17:713-722.