

mActive: A Randomized Clinical Trial of an Automated mHealth Intervention for Physical Activity Promotion

Seth S. Martin, MD, MHS; David I. Feldman, BS; Roger S. Blumenthal, MD; Steven R. Jones, MD; Wendy S. Post, MD, MS; Rebeccah A. McKibben, MD, MPH; Erin D. Michos, MD, MHS; Chiadi E. Ndumele, MD, MHS; Elizabeth V. Ratchford, MD; Josef Coresh, MD, PhD; Michael J. Blaha, MD, MPH

Background—We hypothesized that a fully automated mobile health (mHealth) intervention with tracking and texting components would increase physical activity.

Methods and Results—mActive enrolled smartphone users aged 18 to 69 years at an ambulatory cardiology center in Baltimore, Maryland. We used sequential randomization to evaluate the intervention's 2 core components. After establishing baseline activity during a blinded run-in (week 1), in phase I (weeks 2 to 3), we randomized 2:1 to unblinded versus blinded tracking. Unblinding allowed continuous access to activity data through a smartphone interface. In phase II (weeks 4 to 5), we randomized unblinded participants 1:1 to smart texts versus no texts. Smart texts provided smartphone-delivered coaching 3 times/day aimed at individual encouragement and fostering feedback loops by a fully automated, physician-written, theory-based algorithm using real-time activity data and 16 personal factors with a 10 000 steps/day goal. Forty-eight outpatients (46% women, 21% nonwhite) enrolled with a mean±SD age of 58±8 years, body mass index of 31±6 kg/m², and baseline activity of 9670±4350 steps/day. Daily activity data capture was 97.4%. The phase I change in activity was nonsignificantly higher in unblinded participants versus blinded controls by 1024 daily steps (95% confidence interval [CI], −580 to 2628; *P*=0.21). In phase II, participants receiving texts increased their daily steps over those not receiving texts by 2534 (95% CI, 1318 to 3750; *P*<0.001) and over blinded controls by 3376 (95% CI, 1951 to 4801; *P*<0.001).

Conclusions—An automated tracking-texting intervention increased physical activity with, but not without, the texting component. These results support new mHealth tracking technologies as facilitators in need of behavior change drivers.

Clinical Trial Registration—URL: <http://ClinicalTrials.gov/>. Unique identifier: NCT01917812. (*J Am Heart Assoc.* 2015;4:e002239 doi: 10.1161/JAHA.115.002239)

Key Words: accelerometer • activity tracker • automation • cardiovascular disease • digital health • eHealth • health technology • mHealth • mobile phone • pedometer • physical activity • prevention • smartphone • text messages • texting • wearable device • wearable sensor

Physical activity is a central element of lifestyle guideline recommendations for the prevention of cardiovascular disease (CVD) and one of the health behaviors targeted by the American Heart Association's (AHA's) 2020 Strategic Impact Goals.^{1,2} However, it is estimated that >50% of U.S.

adults do not obtain ideal levels of physical activity, a statistic that has not significantly changed in National Health and Nutrition Examination Surveys since 1988–1994.³ Therefore, new approaches to physical activity promotion are needed.

From the Ciccarone Center for the Prevention of Heart Disease, Johns Hopkins University School of Medicine, Baltimore, MD (S.S.M., D.I.F., R.S.B., S.R.J., W.S.P., R.A.M., E.D.M., C.E.N., E.V.R., M.J.B.); Welch Center for Prevention, Epidemiology, and Clinical Research, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD (S.S.M., W.S.P., R.A.M., E.D.M., C.E.N., J.C.).

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Correspondence to: Seth S. Martin, MD, MHS, Johns Hopkins Hospital, 600 N. Wolfe St, Carnegie 591, Baltimore, MD 21287. E-mail: smart100@jhmi.edu

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Miniaturization and other advances in mobile health (mHealth) technology have enabled convenient and accurate tracking of physical activity through smartphone applications and wearable devices.⁴ Whereas in the past one would have to manually record daily activity when using a traditional pedometer, new technology automatically produces a digital activity log. In addition to streamlining self-monitoring, the vast consumer adoption of these technologies has opened a new channel to deliver continuous feedback aimed at stimulating healthy behavior change.^{4–7} The AHA's Scientific Statements on mHealth and interventions to promote activity have identified a critical need for rigorous studies of new mHealth techniques.^{7,8}

In this context, we conducted a randomized, clinical trial (“mActive”) testing the hypothesis that a fully automated, fully mobile, and physician-designed mHealth intervention using new technologies to provide individual encouragement and foster feedback loops increases physical activity. The mHealth intervention had 2 core components—tracking and texting—and so we sought to use a trial design that would allow for specific evaluation of the effects of each of these components. Furthermore, we sought to conduct a practical trial maximizing convenience for the participants and investigators so that it would have greater potential to be scaled in future trial phases and adopted in routine care settings.

Methods

Trial Design

The mActive protocol was publically registered before enrollment (clinicaltrials.gov: NCT01917812) and was approved by the Johns Hopkins School of Medicine Institutional Review Board. We used sequential randomization to individually evaluate the tracking and texting components of the intervention. After establishing baseline activity during a blinded run-in (week 1), in phase I (weeks 2 to 3) we randomized 2:1 to unblinded versus blinded tracking. The activity tracker itself did not show activity information, but continuously transmitted it in all participants. The activity data were only visible to those who were unblinded, as further described below. In phase II (weeks 4 to 5), we randomized unblinded participants 1:1 to “smart texts” versus no texts. Smart texts were automated, personalized, smartphone-delivered coaching messages informed by real-time activity and other factors, as described in detail below.

Participants

We enrolled outpatients at an academic CVD prevention center in Baltimore, Maryland from January 17 to May 20,

2014. We included patients aged 18 to 69 years who were using a Fitbug-compatible smartphone (ie, iPhone \geq 4S, Galaxy \geq S3). Intending to mainly modify leisure-time activity, we targeted individuals reporting <3 days/week of moderate or vigorous leisure-time activity lasting ≥ 30 min/day by the long form of the International Physical Activity Questionnaire (IPAQ).⁹ Validation of the questionnaire up to 69 years of age served as the rationale for the trial's upper age limit. We did not have an eligibility restriction based on smartphone or Internet literacy, although all subjects confirmed having access to e-mail for pertinent trial communication. We recorded demographic and clinical characteristics, including dog ownership, because it is thought to have a positive effect on the owner by modifying their cognitive beliefs about walking, providing motivation, and providing social support for walking.¹⁰ All patients continued to receive routine care and gave written informed consent. Face-to-face visits were not required after enrollment.

Interventions

Participants used their own smartphones. Digital physical activity tracking was performed using the Fitbug Orb (Chicago, IL) (Figure S1), a wearable, display-free, triaxial accelerometer that pairs with low-energy Bluetooth with compatible smartphones. The 3V lithium battery lasts around 6 months and thus did not require charging or replacement during the trial. Unblinded patients could continuously view their daily step count, activity time, and aerobic activity time through smartphone and Web interfaces (Figure S2). The Fitbug app also provided a history tab allowing review of data from previous days. Activity data were updated every 15 minutes if transmission occurred by beacon mode or were available any time if a participant activated a manual data push or streaming mode.

To enable real-time activity data to inform smart texts, we linked the application programming interfaces of Fitbug and a smart texting system (Reify, Baltimore, MD). Smart text content was written by the physician investigators and reflected behavioral change theories,¹¹ particularly of feedback loops and habit formation,¹² integrated with cardiovascular knowledge and clinical experience. Smart texts took into account the importance of prescription writing and having a specific, proximal goal; we used a goal of 10 000 steps/day.^{8,13–15} Each participant was a patient of a study physician with texts aiming to leverage the physician-patient relationship, using the physician's name in texts. Messages underwent content iterations to optimize language during pretrial testing by the study team.

Smart texts were grouped as positive reinforcement messages, sent when a participant was on track to attain or had already attained his or her daily goal, and booster messages, to motivate individuals when they were not

tracking to surpass their step goal. According to the preprogrammed algorithm, smart texts were sent 3 times/day (morning, mid-day, and evening), with exact times customized to the participant's usual wake time, lunch time, and beginning of evening leisure time. On the day of enrollment, all participants completed an online questionnaire (Table S1) to provide information on 16 personal and clinical characteristics, which was later used for personalizing text messages within the texting arm. Specific examples of text messages are shown in Table S2.

Outcomes

We considered the AHA's Scientific Statement on assessing physical activity for clinical and research applications.¹⁶ Given the setting-specific resources and technology capabilities, and common clinical focus on step count, we set our primary outcome measure as the mean change in accelerometer-measured daily step count assessed from baseline through phase I and II. In addition to this continuous outcome measure, we examined attainment of the prescribed 10 000 steps/day goal. Secondary activity outcome measures were changes in total daily activity time and aerobic time. Aerobic time was defined as the time spent walking continuously for >10 minutes without breaking for >1 minute. Additionally, we assessed participant satisfaction through an online survey, with qualitative and quantitative elements, upon trial completion.

Statistical Analysis

We estimated that the sample size needed to detect at least a 2000-step difference in means was 14 participants per group, or 42 participants total, assuming a within-participant SD of 1800 steps/day, 2-sided alpha of 0.05, and beta of 0.8. Allowing for 12% attrition, target enrollment was 48 participants. Our trial aimed to detect an increase of 2000 steps/day, given that this was previously associated with a \approx 10% relative reduction in the long-term incidence of CVD,¹⁷ and is generally felt to represent a clinically significant increase. However, the selection of 2000 steps/day does not signify that a smaller increase in physical activity could not also be clinically significant.

Baseline characteristics were summarized using descriptive statistics—frequency (percentage) for categorical data and mean (standard deviation) for continuous data. All outcomes were compared between treatment arms by intention to treat. We used repeated measures analysis of variance for mean comparison tests and calculated 95% confidence intervals (CIs). For comparisons of proportions, we used Fisher's exact test because of small cell sizes. Exploratory subgroup interaction testing was performed to

examine for heterogeneity in treatment effect by age, sex, race, body mass index (BMI), diabetes, hypertension, dyslipidemia, coronary heart disease (CHD), dog ownership, marital status, employment, or baseline activity. Statistical analyses were performed using Stata software (version 11.1; StataCorp LP, College Station, TX).

Reporting

We followed the Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and onLine TeleHealth (CONSORT-EHEALTH).¹⁸ Most elements are reported here, with additional details on CONSORT-EHEALTH items provided in Table S3.

Results

Participant and Data Flow

The trial flow diagram is shown in Figure 1. Of 50 eligible individuals, 48 (96%) enrolled. There was no early dropout and all participants in the intervention arms completed the protocol. One blinded participant had data transmission issues in phase II and elected not to complete the protocol. Daily activity data capture was 97.4%.

Baseline Characteristics

There were no significant baseline differences between groups (Table 1). Overall, participants were age 58 ± 8 years, nearly evenly split by sex, and 21% nonwhite. Eighty-eight percent were employed, primarily in management and professional occupations. The majority of participants were obese, 23% had diabetes, and 29% CHD. Baseline activity levels were 9670 ± 4350 steps/day, 93 ± 45 min/day, and 13 ± 18 aerobic min/day.

Primary Outcome: Change in Steps/Day

Physical activity trajectories were different among the 3 trial groups. The blinded group showed a progressive downward trend over the whole time period, particularly in the change from phase I to II. This downward drift was not observed in either of 2 other trial groups. The unblinded arm trajectory was characterized by a maintenance of baseline activity levels, whereas the biggest shift in trajectory was noted in the text-receiving arm. This group had a clear upward trend in physical activity in response to smart texts.

In phase I (Table 2), blinded control participants obtained a mean of 616 fewer steps/day (6% decrease) whereas unblinded participants increased their steps/day by a mean of 408 (4% increase). The between-group differential was

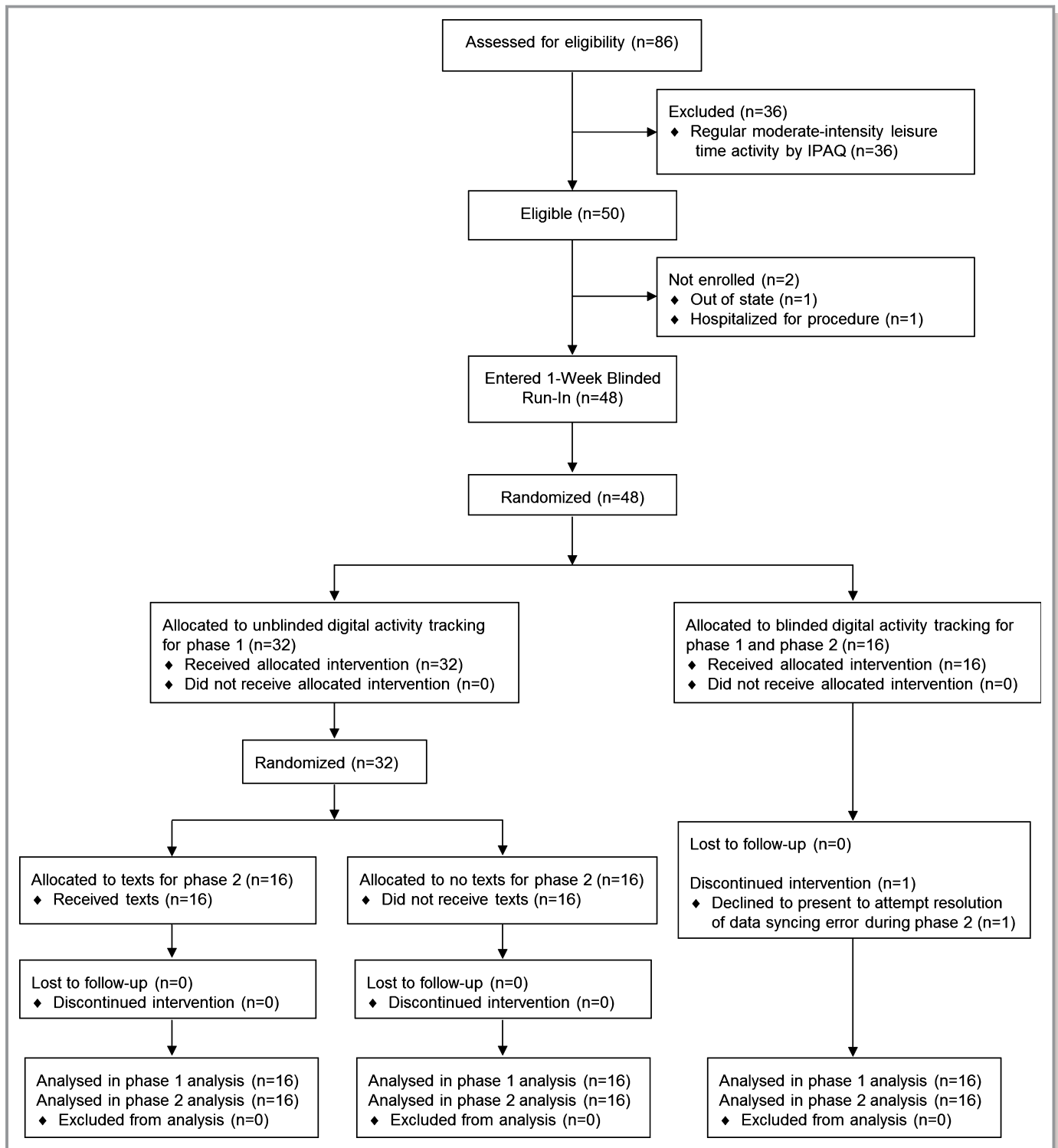


Figure 1. mActive trial flow diagram. IPAQ indicates International Physical Activity Questionnaire, Long-Form.

nonsignificantly higher in the unblinded group versus blinded controls by 1024 steps/day (95% CI, -580 to 2628; $P=0.21$).

In phase II (Table 2), the blinded group further decreased its activity by 1042 steps/day (11% decrease) whereas the unblinded–no texts group decreased by 200 steps/day (<1%

change). In contrast, the unblinded-texts group obtained 2334 more steps/day (25% increase). The differential in activity levels was significant; participants receiving texts increased their daily steps over those not receiving texts by 2534 (95% CI, 1318–3750; $P<0.001$) and over blinded controls by 3376 (95% CI, 1951 to 4801; $P<0.001$).

Table 1. Baseline Characteristics of mActive Trial Participants

	All Participants (n=48) No. (%)	Unblind (n=32)		Blind (n=16) No. (%)
		No Texts (n=16) No. (%)	Texts (n=16) No. (%)	
Age, y, mean±SD	58±8	58±8	55±8	60±7
Sex				
Men	26 (54)	9 (56)	8 (50)	9 (56)
Women	22 (46)	7 (44)	8 (50)	7 (44)
White race	38 (79)	12 (75)	12 (75)	14 (88)
Dog owner	21 (44)	9 (56)	5 (31)	7 (44)
Married	35 (73)	13 (81)	9 (56)	13 (81)
Employed	42 (88)	13 (81)	15 (94)	13 (81)
Management, professional*				
Service	30 (63)	9 (56)	9 (56)	12 (75)
Sales, office				
Construction, maintenance	5 (10)	2 (13)	3 (19)	0 (0)
Construction, maintenance				
CHD	2 (4)	0 (0)	1 (6)	1 (6)
CHD	14 (29)	5 (31)	2 (13)	7 (44)
Diabetes	11 (23)	5 (31)	2 (13)	4 (25)
Smoker	1 (2)	1 (6)	0 (0)	0 (0)
Hypertension	24 (50)	8 (50)	5 (31)	11 (69)
Dyslipidemia	39 (81)	14 (88)	12 (75)	13 (81)
BMI kg/m ² , mean±SD				
≥30	31±6	30±5	30±7	33±7
≥30	26 (54)	7 (44)	9 (56)	10 (63)
IPAQ [†]				
Low	10 (21)	2 (12)	3 (19)	5 (31)
Moderate	21 (44)	7 (44)	9 (56)	5 (31)
High	17 (35)	7 (44)	4 (25)	6 (38)

BMI indicates body mass index; CHD, coronary heart disease; IPAQ, International Physical Activity Questionnaire, Long-Form.

*Types of employment per U.S. Census Bureau definitions.

[†]Represents total activity; all subjects reported low leisure time activity per the IPAQ.

At baseline, 23 (48%) participants had a daily step count ≥10 000 steps/day, 9 (56%) in the blinded group and 14 (44%) in the unblinded group (Figure 2). In phase I, the ≥10 000 step/day goal was attained by 1 less participant in both the blinded group (8 of 16; 50%) and unblinded group (13 of 32; 41%). In phase II, the number of participants meeting the 10 000 steps/day goal was 7 (44%) in both the blinded- and unblinded–no texts groups. In contrast, 13 (81%) participants who were unblinded and receiving smart texts achieved a daily step count ≥10 000 steps/day (37% absolute increase and 84% relative increase over other groups; *P*=0.02).

Secondary Outcomes: Total and Aerobic Activity Times

In phase I (Table 2), the unblinded and blinded groups were not significantly different in modifying their total activity times, whereas there was a borderline significant smaller decrease in aerobic time in unblinded patients (differential 8 minutes; 95% CI, 0 to 16; *P*=0.05). In phase II, activity times continued to decrease in the blinded group and remained relatively stable in the unblinded–no texts group. In contrast, the unblinded–texts group increased its total activity time by 21 min/day (23% increase) and aerobic time by 13 min/day (160% increase), which was highly statistically significant compared to the other groups.

Exploratory Subgroup Interaction Testing

For the interaction of the phase I intervention (unblinding) with a given patient factor, *P* values for interaction were as follows: 0.36 for age; 0.53 for sex; 0.67 for race; 0.17 for BMI; 0.46 for diabetes; 0.83 for hypertension; 0.51 for dyslipidemia; 0.63 for CHD; 0.70 for dog ownership; 0.99 for marital status; 0.46 for employment; and 0.20 for baseline activity. Interaction testing was similarly null for the secondary outcomes of total activity time and aerobic time. The respective *P* values for the interaction of the phase II intervention (smart texts) were also null for most patient factors as follows: 0.59 for age; 0.60 for race; 0.35 for BMI; 0.45 for diabetes; 0.29 for hypertension; 0.41 for dyslipidemia; 0.14 for dog ownership; 0.68 for marital status; 0.72 for employment; and 0.93 for baseline activity.

However, there was a trend for significant interaction by sex (*P*=0.06), with women showing a 3754 steps/day increase (95% CI, 2189 to 5319) in response to smart texts as compared with men, who showed a 1562 steps/day increase (95% CI, –209 to 3334). Similar results were observed for the interaction of total time and sex (*P*=0.05), with responsiveness to text messaging predominantly found in women (35 min/day; 95% CI: 20 to 50) rather than in men (10 min/day; 95% CI, –10 to 30). In contrast, an interaction was not observed between aerobic time and sex (*P*=0.58).

There was a significant interaction by CHD status (*P*=0.03). Those with coronary disease increased their physical activity by 5068 steps/day (95% CI, 1371 to 8765) in response to smart texts as compared to 1777 steps/day (95% CI, 489 to 3065 steps/day) in others. There was a similar interaction by CHD status for the secondary outcome of total activity time (*P*=0.04). The group with versus without known coronary disease increased physical activity time by 50 min/day (95% CI, 4 to 95) versus 14 min/day (95% CI, 0 to 28). For the outcome of aerobic time, however, no significant interaction was present (*P*=0.90).

Table 2. Changes in Activity Outcomes With Phase I and II Interventions

	Unblind (n=32) Mean Change±SD	Blind (n=16) Mean Change±SD	Unblind-Blind Mean Difference (95% CI), P Value			
Phase I						
Steps, count/day*	408±2701	-616±2385	1024 (-580 to 2628), P=0.21			
Activity time, min/day	2±27	-6±26	8 (-9 to 25), P=0.33			
Aerobic time, min/day	-3±12	-11±14	8 (0-16), P=0.05			
	Texts (n=16)	No Texts (n=16)	Blind (n=16)	Texts-No Texts	Texts-Blind	No Texts-Blind
	Mean Change±SD			Mean Difference (95% CI), P-value		
Phase II						
Steps, count/day*	2334±1714	-200±1653	-1042±2202	2534 (1318-3750), P<0.001	3376 (1951-4801), P<0.001	842 (-564 to 2248), P=0.23
Activity time, min/day	21±20	0±17	-8±23	21 (8-34), P=0.003	29 (13-45), P<0.001	8 (-7 to 23), P=0.28
Aerobic time, min/day	13±11	-1±8	-3±10	14 (7-21), P<0.001	16 (7-23), P<0.001	2 (-6 to 8), P=0.71

*Primary outcome. CI indicates confidence interval.

Satisfaction

On post-trial surveys, participants largely expressed feelings of satisfaction and enthusiasm for future trial participation. Quantitatively, participants assigned the activity tracker a mean score of 4.0 of 5.0, and text messages 3.8 of 5.0 (4=good; 5=great).

Discussion

In mActive, coupling smart texts with activity tracking led to the best physical activity outcomes. Nearly twice as many participants in the text-receiving arm achieved the 10 000 steps/day goal compared with the other groups. Aerobic activity levels were disproportionately low compared with steps and total activity time, but appeared most responsive to intervention. The mActive trial lends support to the notion of new mHealth devices as facilitators, not drivers, of behavior change,⁶ because sequential randomization suggested that unblinding to device data did not significantly modify behavior, whereas coupling it with smart texts did.

If sustained, the change in physical activity from the mActive tracking-texting intervention may be clinically significant. A comparable step count increase over a mean duration of 18 weeks was associated with significant decreases in BMI and systolic blood pressure.¹⁴ During a mean of 6 years, each 2000 step/day increase in physical activity was associated with a ≈10% relative reduction in the incidence of CVD.¹⁷ Sustaining regular physical activity over the long term is associated with a more favorable circulating metabolome¹⁹ and decreased markers of inflammation.²⁰ Benefits of cardiorespiratory fitness may extend to non-CVD diseases, such as cancer, depression, and dementia, with a dose-dependent reduction in all-cause mortality.²¹⁻²⁴

However, the influence of behavioral counseling may be limited in the current health care delivery model wherein clinicians tend to see patients for brief visits every several months or annually.²⁵ Aimed to fill the gap, the mActive system is physician designed and intended to leverage the

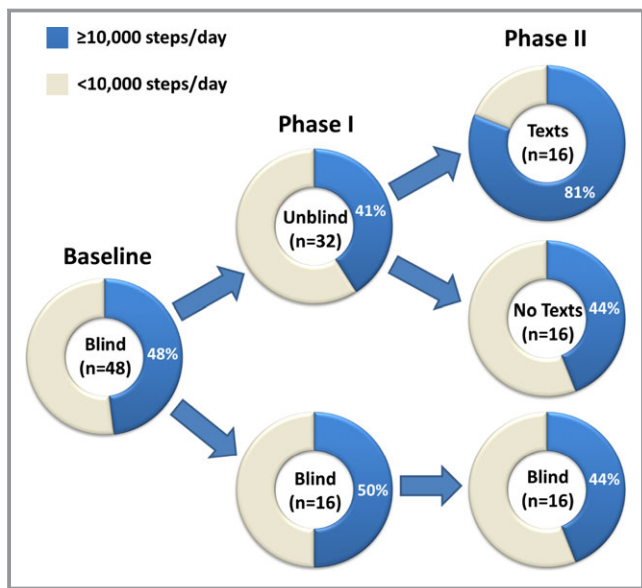


Figure 2. Proportions attaining the 10 000 steps/day goal at baseline, in phase I, and phase II, by intervention group. Forty-eight percent of participants attained the 10 000 step/day goal at baseline. No significant change or between-group difference was observed in phase I, whereas in phase II, the unblinded-texts group showed a 37% absolute increase and 84% relative increase over other groups in 10 000 steps/day attainment (P=0.02).

clinician-patient relationship while functioning automatically without day-to-day involvement of the physician. Compatible with the importance of smart text support, pedometer-based interventions without smart texts did not benefit insurance company employees in Finland²⁶ or adults with diabetes in southwest England.²⁷

mActive also appears to provide a significant advance over previous Web-based approaches, which have produced mixed results.^{8,28–30} We are aware of another group aiming to send mobile phone text messages³¹ based on activity tracking; distinct from the mActive mobile design, it relies on computer access points for data transmission. mActive moves the field forward by providing the first fully mobile, fully automated, physician-designed, integrated tracking-texting intervention, with potential to modify behavior in real time, while also being potentially reproducible, affordable, and widely scalable. Enhancing such prospects, activity tracking apps built into smartphones are now common, and our technique could be applied using them. Our technique might also enhance the development of cardiac rehabilitation programs using mHealth.³² Overall, our resource-efficient strategy may facilitate more continuous monitoring and feedback between the health system and patients.

mActive presents an attractive new paradigm for patient-oriented research as a union of the strengths of mHealth and randomization. We suspect that the convenience offered by the truly mobile mActive design may have benefitted recruitment, retention, and data capture. The trial met its recruitment target, enrolled 96% of eligible patients (as compared to the typical statistic of around 50%³³), and all patients but 1 completed the protocol. Without specifically targeting recruitment of women, the mActive trial had nearly equal representation of men and women. The mActive trial recruitment experience supports the data-driven hypothesis³³ that a trial design fostering convenience can enhance trial participation. Furthermore, there was a very high level of physical activity outcome completeness obtained using a digital approach.

Limitations

Given its limited size and scope, mActive may be categorized as a pilot trial. As such, it is most appropriately interpreted as exploratory evidence to guide a definitive pivotal trial in the future.³⁴ The trial provides a solid basis to build upon given that it was conducted using the rigorous scientific methodology characteristic of pivotal randomized, clinical trials, including public registration and incorporation of randomization and blinding. Whereas our trial detected an effect only when smart texts were added to activity tracking, with a larger sample size, less within-person variability (within-person SD exceeded our estimate of 1800 steps/

day), or a longer duration of intervention, activity tracking alone may have led to a statistically significant increase in physical activity. Greater power could also allow more-definitive examination of potential moderators of treatment. Our subgroup analyses were exploratory in nature and underpowered, but produced intriguing signals by sex and coronary disease status, which can be considered by future studies. To address the limited duration of follow-up in mActive, we plan to perform long-term follow-up of participants for physical activity outcomes and risk factors (eg, BMI and blood pressure). Additionally, we are creating additional smart text content to allow for longer-term interventions.

Generalizability remains uncertain for multiple reasons. Participants were adult smartphone users from a single preventive cardiology clinic and may have been highly motivated because of obesity, other CVD risk factors, or known CVD. Behavioral influences also potentially arose from attention on participation in a physical activity trial, awareness of being observed (Hawthorne effect), and investigator expectations (Rosenthal effect). In total, these factors may explain the unexpectedly high physical activity levels at baseline and throughout the trial in the trial participants as a whole (further discussion in Table S3, 19-ii).

Finally, it may be considered a limitation that we did not use human coaches as part of the intervention. There may be added value in what a human coach could provide, for example, through motivational interviewing. On the other hand, it could be considered a strength given that the automated approach may be more reproducible and more easily scaled at lower cost.

Conclusion

In ambulatory cardiology patients who are smartphone users, a novel mHealth intervention coupling smart texts to digital tracking significantly increased near-term physical activity. The effect was dependent on the text message component of the intervention. This pilot trial gives insight into the efficacy and feasibility of components of the mHealth intervention and provides an initial step forward in a rapidly growing area in critical need of high-quality clinical evidence. Ultimately, therapeutic implications await larger, multicenter, definitive pivotal trials involving more-diverse groups of patients.

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Disclosures

Digital physical activity tracking devices were provided in kind by Fitbug, a private for-profit company. This trial was investigator initiated and Fitbug did not provide cash payments for the research or writing of the manuscript. Fitbug did not participate in the analysis of the data or influence the conclusions.

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