

Original Research

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Evaluating the feasibility and effectiveness of self-monitoring of health among Samoan women: a randomized trial.

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ABSTRACT

Introduction: Self-monitoring technologies that help individuals track their health have proven effective in high-income countries but have not been widely tested or marketed in the Pacific. We conducted a pilot randomized controlled trial in Samoa to investigate the feasibility and acceptability of step-counters and digital scales.

Methods: The trial enrolled 44 Samoan women (31-40 years), without previously diagnosed chronic conditions (hypertension, diabetes, etc.), who reported motivation to become more physically active. After measuring daily step counts for one week in the absence of feedback, participants were randomly assigned to one of three groups for a four-week intervention period: 1) FitBit Zip® step-counter, 2) digital BodyTrace® scale, or 3) both devices. Outcomes of interest were device use, psychosocial indicators of health, daily step counts, and body mass index, measured at baseline and post-intervention.

Findings: Participants who received scales used them a median of 5.5 times during the four-week intervention period. While FitBits were used a majority of days during the baseline period, there was significant decline in use during the intervention. In all groups, Health Locus of Control, Self-Efficacy for Exercise, and Weight Efficacy improved. However, while the Scale Only group reported improved health-related quality of life, the two groups that used FitBits either did not significantly change or significantly decreased in their assessments of this measure. No group demonstrated change in average daily step counts during the intervention; BMI increased among the two groups using the scales.

Conclusions: Results suggest that self-monitoring technologies are acceptable in Samoa and generally improve psychosocial indicators of health. Further research is necessary to assess their effectiveness as an intervention tool and to determine how best to sustain device use over time. The significant increase in BMI over the relatively short intervention period highlights the importance of developing effective intervention approaches in this setting.

Key Words: Samoa, Exercise, Body Mass Index, Psychosocial Factors, Self-monitoring

INTRODUCTION

The global non-communicable disease (NCD) epidemic is especially severe among Pacific Islanders, and in Samoa specifically. A 2010 study estimated that 64.6% of adult women and 41.2% of adult men in Samoa had obesity, based on Polynesian Body Mass Index (BMI) cut offs (≥ 32 kg/m²).^{1,2} In recent decades, traditionally active lifestyles and diets have been replaced with increasingly sedentary lifestyles and imported and processed foods, contributing to the high prevalence of obesity observed today.³⁻⁸ Despite Samoan culture traditionally valuing sedentary behavior as a sign of status, there has been evidence of recent adoption of varied physical activity programs (Zumba, cross-fit, yoga) as a means of health promotion.^{5,6}

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Innovative approaches that encourage adoption and maintenance of physical activity are needed to support this positive momentum.

Many effective behavior change and weight control interventions (tested in high income settings) have incorporated self-monitoring of physical activity and weight.⁹⁻¹³ Self-monitoring strategies for physical activity have ranged from keeping a paper diary to using tracking devices including pedometers, used to record walking behaviors. Basic pedometers are low-tech, affordable, and provide a simple output, usually step count, that can help users be more aware of their physical activity and track progress toward goals.¹⁴ Self-weighing similarly improves participant's awareness of their own weight, which is often underestimated and encourages them to place fluctuations in weight in the context of their energy intake and expenditure.^{11,15,16}

Despite the success of self-monitoring approaches and technologies in high-income countries, the acceptability and effectiveness of these strategies in the Pacific is still unknown. Given the confluence of the need for intervention and increasing accessibility of this technology in Samoa, we conducted a randomized intervention trial to answer the questions: are step-counters and digital scales a feasible and potentially effective means of self-monitoring health, altering daily step counts, and influencing BMI in Samoa?

METHODS

Recruitment

Participants in this study were part of the 'Soifua Manuia' ('Good Health') energy balance study, which was designed to examine the relationship between genetics, energy balance, and obesity in Samoa.¹⁷ The initial recruitment phase of that study, completed between June and August 2018, screened 709 adult Samoans aged 31 to 50 years using convenience sampling in 12 villages across the island of Upolu. Exclusion criteria for the parent study included: pregnancy, use of weight loss medication, recent adoption of a diet or exercise program, and/or weight loss of at least 5% of their body weight in the last year. Data collected included demographic and health surveys, anthropometric measurements, blood pressure, glycated hemoglobin (HbA1c), and a saliva sample for genotyping. During the informed consent process participants agreed to be contacted about participation in future research studies.

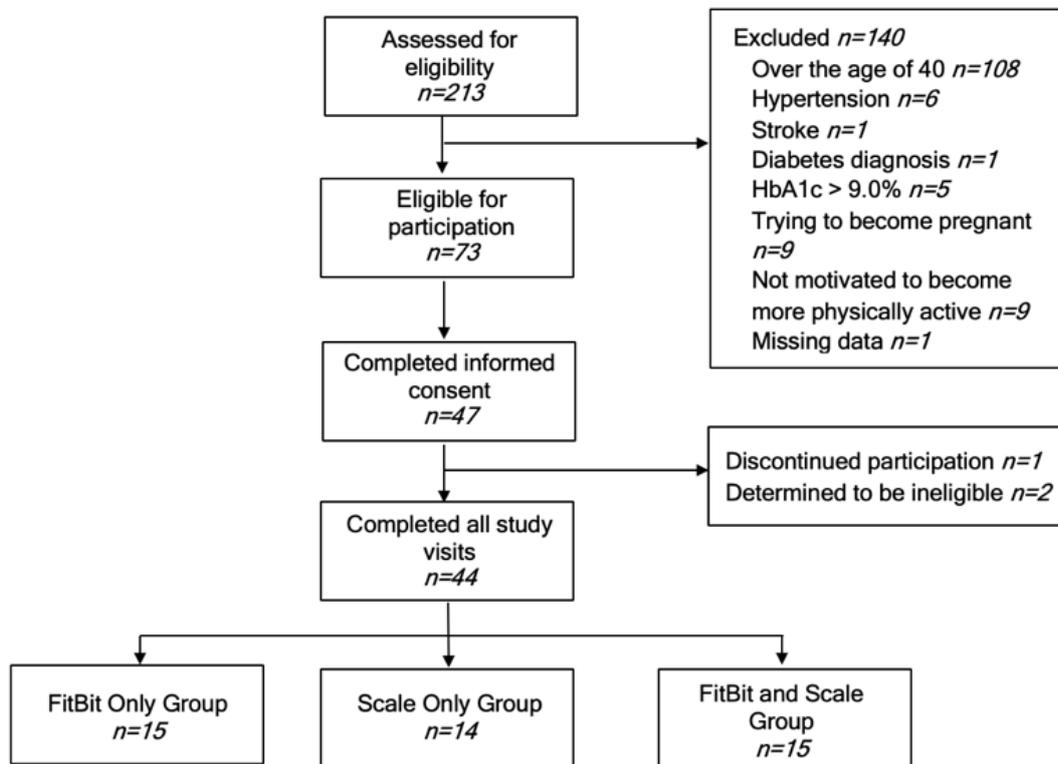
Eligibility for this pilot study was determined based on data collected in the recruitment phase of the energy balance study. Women between the ages of 31 and 40 years (to minimize variation in this small pilot study), who reported motivation to become more physically active (defined by the Physical Activity Stages of Change questionnaire¹⁸), and were not actively trying to become pregnant/had no medical condition preventing physical activity or making participation inadvisable were invited to participate. Excluded medical conditions were self-report of doctor diagnoses including hypertension, heart attack, heart disease, stroke, Type 2 diabetes, non-skin cancers, and dialysis, all of which may limit normal physical activity patterns. Participants were also excluded if they were not previously diagnosed with diabetes but their HbA1C measurement during screening suggested that they had severely uncontrolled Type 2 diabetes (HbA1c ≥ 9.0), if they had been hospitalized for depression in the last year, were being treated for psychiatric conditions other than depression, had been previously diagnosed with an eating disorder, or were unable to walk half a kilometer without stopping.

Participants were recruited from four villages in close proximity to the Apia Urban Area to facilitate follow up. Among those screened for the energy balance study, 213 women were between the ages of 31-40 years and were assessed for eligibility; 73 met criteria for participation (**Figure 1**). These participants were contacted by members of our research team and offered the opportunity to participate in this additional study. It was made clear that participation would be voluntary and unrelated to the ongoing study from which they were originally recruited. Study procedures were approved by the Yale University IRB (HSC Protocol #2000022946) and the Samoan Ministry of Health's Health Research Committee. The study protocol was also registered with ClinicalTrials.gov (Identifier: NCT03940599, Registered 07 May 2019 - Retrospectively registered.)

Equipment

Two types of devices were utilized in the study: FitBit Zip[®] activity monitors (Fitbit Inc, USA), and BodyTrace[®] scales.¹⁹ FitBit Zips[®] are electronic, waist-worn pedometers that measure and display daily step counts. Each FitBit linked to an online account, which the research team retained access to and used to upload device data via Bluetooth. The BodyTrace[®] scales displayed weight measurements to the participant and transmitted the recorded weights to an online database through cellular networks, allowing researchers to track scale use.

Figure 1: CONSORT Flow Diagram



Intervention

Participants were enrolled in the study by Samoan research assistants who visited participants in their homes in June and July 2018. After providing informed consent, all participants began a one-week baseline assessment period. Each received a FitBit Zip with the screen covered (screens were covered with tape and the devices reversed in their belt clips) to prevent their behavior from being influenced by the step count data, and were asked to wear the device daily (any time they were not sleeping overnight) to establish their baseline physical activity.

After the one-week baseline assessment, participants' weight was measured to calculate pre-randomization body mass index (BMI). Participants also completed questionnaire measures to assess psychosocial indicators of health. The Multidimensional Health Locus of Control Scale (HLOC) was used to measure: an individual's perceived control of their own health (Internal), the influence of random luck (Chance), and the influence of others such as friends, family, and medical providers (Powerful Others).²⁰ The Self-efficacy for Exercise Behaviors Scale and the Weight Efficacy Life-Style Questionnaire assessed individuals' beliefs about their ability to adopt and maintain a

healthy diet and physical activity in the face of obstacles, including stressful life events and familial obligations.^{21,22} The SF8 Quality of Life scale asked individuals to assess their physical and mental health over the last month, and a self-reported health question asked individuals to assess their overall health for their age (Excellent, Very Good, Good, Poor, and Very Poor). All questionnaires had been used in prior studies among Samoan adults and had been translated and pilot-tested in this setting.

After completing the questionnaires, a random number generator was used to assign participants to one of three intervention groups: 1) FitBit Only (n=15), 2) Scale Only (n=15), or 3) FitBit and Scale (n=15). All participants wore FitBits for the duration of the intervention period to measure their physical activity; the screens were uncovered for the groups assigned to self-monitor using the FitBits, but they remained covered in the Scale Only group. Participants then used the devices for a four-week intervention period. Because the primary purpose of the study was to explore how participants in this setting viewed and made use of these devices, participants were shown how to use the devices, but were not provided with specific targets related to daily step counts or weight.

The research team visited participants once at approximately the midpoint of the four-week intervention period to download data from the FitBits. This visit did not include any additional surveys or any feedback on the outcomes of interest. At the end of the intervention period, participants repeated the same questionnaires and physical measurements. Upon completion, participants received approximately USD\$12 in cell phone credit to compensate them for their time and were able to keep the FitBit Zip® that they used during the study.

Analysis

All analyses were conducted in SAS version 9.4 (SAS Institute Inc., Cary, NC.). Given the small sample size, analyses were conducted using nonparametric methods including Fisher's exact tests for categorical data, Kruskal-Wallis tests for comparisons of the intervention groups, and the Wilcoxon Signed-Rank test for comparisons of measures between the baseline and feedback periods.

FitBit use was defined as the proportion of days in the given period that the individual participant wore the FitBit. A day of use was defined as the FitBit recording more than 100 steps to ensure the measurement was not only reflecting accidental movement or transport while not being worn. A previous feasibility study conducted in Australia utilized a 1,000 step threshold for a day to count.²³ Given the lack of previous data about average step counts in this population, we selected a lower threshold. An individual's daily step count for each week of the study period was averaged over the days that they used the FitBit. Participants were excluded from the step count analysis if they were missing data for an entire week, either due to non-adherence, losing the FitBit, or device malfunction.

Scale use was defined as the number of measurements that an individual made on the BodyTrace® scale during the 4-week intervention period. To identify the measurements that were taken by the participant as opposed to another individual in the household, a consensus approach was taken. Two reviewers (NH and EK) assessed measurements independently to identify the participant's measures and met to resolve any conflicts. Measurements were determined to be the participant based on their initial weight, their weight gain trajectory, and the feasibility of weight change over time. Measurements were included as belonging to the participant if they

were within two kilograms of the previous measurement, taking into account time between measurements.

RESULTS

Sample Characteristics

Forty-four participants were assigned to an intervention group (FitBit Only, n=15; Scale Only, n=14; Scale & FitBit, n=15) and completed all study visits. Three participants enrolled but later declined to participate further or were determined to be ineligible and were withdrawn from participation. Demographic characteristics did not differ between groups at baseline (**Table 1**). Based on Polynesian BMI cut offs, the median BMI for the overall sample (36.9 kg/m²) was in the obese range (≥ 32.0 kg/m²).²

Device Use

There was no significant difference in FitBit use between the three groups during the baseline assessment or intervention. Among all participants, there was a significant decline in use of the FitBits between the baseline and intervention periods (66.7% vs. 47.2% of days, $p < 0.001$) (Table 2); seven participants lost the devices. Participants used their scales a median of 5.5 times during the 4-week intervention period (minimum: 1, maximum: of 26). There was no significant difference in scale use between the two groups that received scales ($p = 0.277$).

Psychosocial Indicators of Health

Post-intervention, there was a significant change in psychosocial indicators of health compared to baseline (**Figure 2**). The median score on each of the HLOC subscales increased by a statistically significant amount in the Scale Only and the combined FitBit and Scale groups. The FitBit Only group had a significant increase in the 'Chance' and 'Powerful Others' subscales, but no significant change in the Internal subscale. Post-intervention the three groups did not differ in their HLOC subscale scores. All three groups significantly increased their Self-efficacy for Exercise post-intervention, with a median increase in score of 16.0 points across all three groups. The FitBit Only and FitBit and Scale groups had a significant increase in Weight-Control Self Efficacy following the intervention of 18.0 and 14.0 respectively, while the Scale Only group had a moderately significant increase of 12.0 ($p = 0.053$).

Table 1: Sample Characteristics

	Overall	FitBit Only	Scale Only	FitBit and Scale	P-Value ¹
	Median (Q1, Q3); n (%)	Median (Q1, Q3); n (%)	Median (Q1, Q3); n (%)	Median (Q1, Q3); n (%)	
Age (years)	<i>n</i> =44 36.3 (34.0, 38.4)	<i>n</i> =15 37.4 (33.6, 39.2)	<i>n</i> =14 36.1 (33.5, 39.0)	<i>n</i> =15 36.2 (34.3, 37.8)	0.847
Education (years)	12.0 (12.0, 13.0)	12.0 (11.0, 13.0)	13.0 (12.0, 13.0)	12.0 (12.0, 13.0)	0.428
Married or Cohabiting	40 (90.9)	13 (86.7)	13 (92.86)	14 (93.3)	0.420
Body Mass Index (kg/m ²)	<i>n</i> =40 36.9 (33.9, 40.1)	<i>n</i> =11 36.9 (27.9, 39.6)	<i>n</i> =14 36.2 (34.4, 39.9)	<i>n</i> =15 37.0 (34.4, 46.9)	0.420

¹ P-values reflect Kruskal-Wallis test for continuous variables and Fisher's Exact test for categorical variables. Sample size varies due to missing data.

Table 2: Device Use

	FitBit Use ¹				P-Value ³	Scale Use ² Median (Q1, Q3)
	Baseline Period	Intervention Period	Change			
Overall <i>n</i> =44	66.7 (50.0, 83.3)	47.2 (31.5, 72.2)	-0.15 (-0.31, -0.01)	<0.001	<i>n</i> =28	5.5 (3.0, 7.0)
FitBit Only <i>n</i> =15	66.7 (50.0, 83.3)	40.7 (35.7, 57.1)	-0.11 (-0.30, -0.04)	0.010		-
Scale Only <i>n</i> =14	83.3 (50.0, 83.3)	53.7 (29.6, 70.4)	-0.17 (-0.30, 0.02)	0.042	<i>n</i> =14	5.0 (2.0, 7.0)
FitBit and Scale <i>n</i> =15	83.3 (50.0, 83.3)	50.0 (14.8, 77.8)	-0.17 (-0.39, 0.06)	0.035	<i>n</i> =14	6.0 (4.0, 7.0)

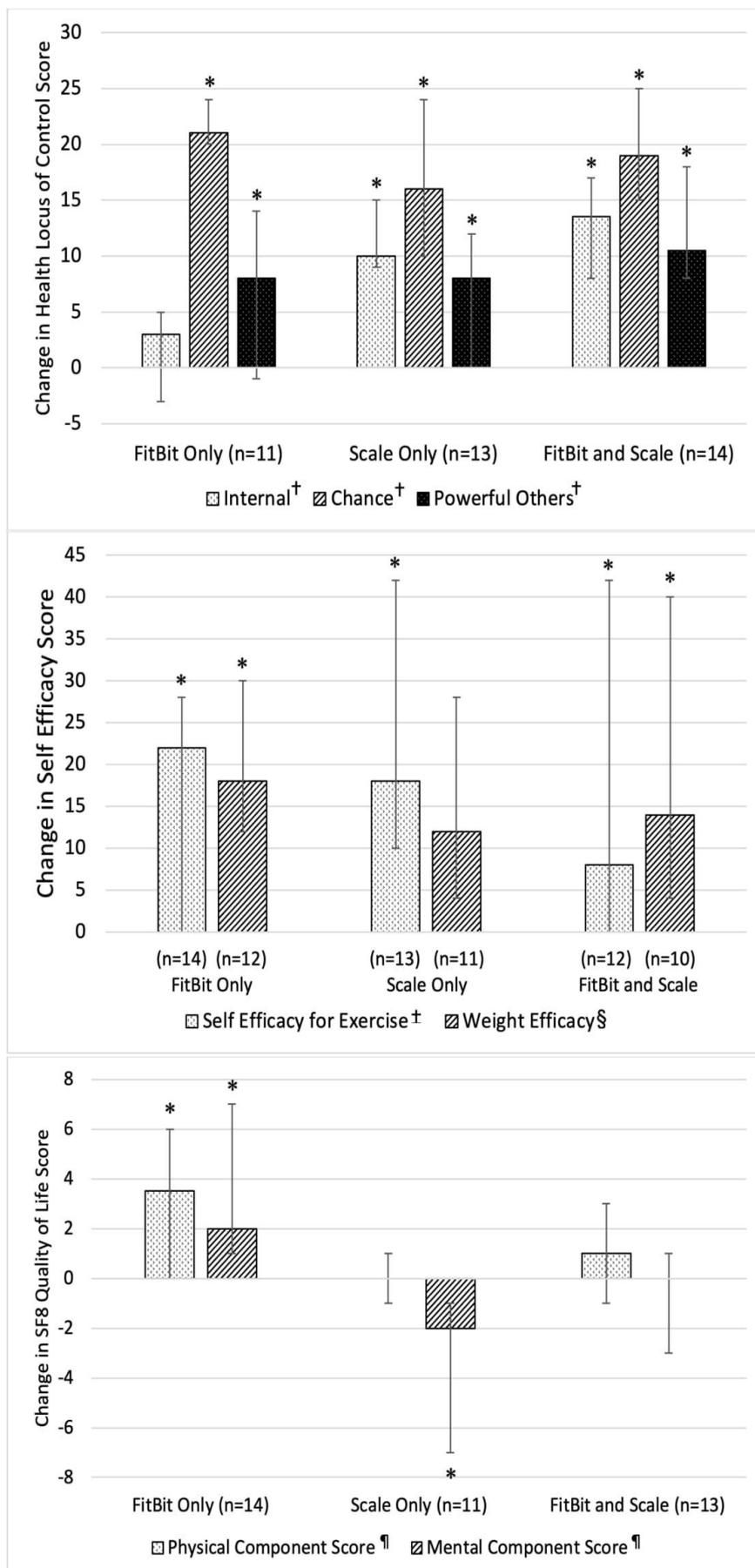
Sample size varies due to missing data.

¹ FitBit use was defined as the proportion of days in the given period that the individual participant wore the FitBit. A day was counted as a day of use if the FitBit recorded more than 100 steps.

² Scale use was defined as the total number of measurements than an individual made on the BodyTrace during the 4-week intervention period.

³ P-values reflect the Kruskal-Wallis test

Figure 2: Change in Psychosocial Indicators of Health



There was also a significant difference in how the groups' self-assessments of health changed during the intervention period. In the FitBit Only group SF-8 scores increased for both physical (2.5 to 6.5, $p=0.002$) and mental (3.0 to 6.0, $p=0.008$) health, indicating worsening quality of life. There were no reported changes in the SF-8 scores of the other two groups. Responding to the self-reported health question, all participants reported that their health was excellent, very good, or good pre-randomization and post-intervention. However, post-intervention the proportion of individuals in the FitBit only group reporting that their health was excellent increased (from 73.3% to 86.7%), while the proportion decreased for the Scale Only (64.3% to 57.1%) and FitBit and Scale groups (80.0% to 33.3%) ($p=0.038$).

* Indicates that the change in score is statistically significant at $\alpha = 0.05$, using the Wilcoxon Signed-Rank test.

† The highest possible score for each HLOC sub scale is 36, with higher scores indicating a greater perceived influence of the specified locus on health.

‡ The highest possible score for the Self Efficacy for Exercise scale is 60, with higher scores indicating greater self efficacy.

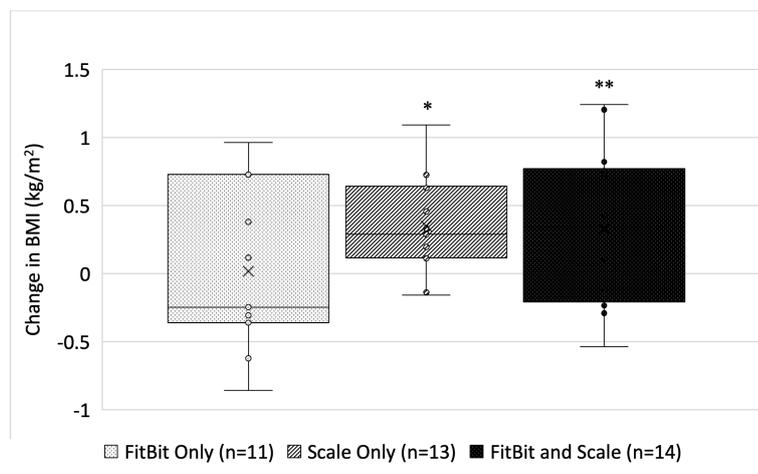
§ The highest possible score for the Weight Efficacy scale is 100, with higher scores indicating greater weight efficacy.

¶ The highest possible score for the physical and mental components is 16 for each subscale, with higher scores indicating a more negative assessment of health-related quality of life.

Physical Activity and BMI

There was no effect of the intervention on physical activity, measured using median daily step counts. Although not significant, the Scale Only and the combined FitBit and Scale groups saw an increase in steps between the baseline and overall intervention periods. A significant increase in BMI between the baseline and post-intervention assessments was observed among the two groups that used scales (Scale Only $p=0.005$, FitBit and Scale $p=0.058$), while the FitBit Only group had a slight, nonsignificant decrease in BMI ($p=0.898$) (Figure 3).

Figure 3: Change in Body Mass Index by Group



* indicates statistically significant median change at $p=0.05$

** indicates a statistically significant median change at $p=0.10$; p -values reflect the result of the Signed Rank Test

DISCUSSION

Based on device use, our results suggest that FitBit step counters and digital scales may be an acceptable intervention tool with a generally promising impact on psychosocial indicators of health. Although there was no clear effect on daily step counts, participants in all groups increased their weight and physical activity-related self-efficacy, a measure known to be associated with successful behavior change. Worryingly, participants in the two groups using the scales increased their BMI during the four-week intervention period, and reported poorer health post-intervention. If the median increase in weight over this four-week study (0.70 kg) were to be extrapolated over a year, the average weight gain observed would be 9.1 kg. This highlights the critical need for weight-related intervention in this setting, but our results indicate that we may need to be cautious about

the psychological impact of the approaches we choose.

Device Use

While FitBit use was high during the baseline period, adherence to daily wear declined in all three groups during the intervention. In our analyses of changes in daily step counts, almost half of the sample had to be excluded due to low adherence, which is of concern. Prior studies assessing the acceptability of pedometers have considered participants' recording step counts at least 70% of the time to indicate 'good' adherence, but these studies often engage participants in other intervention activities, provide step goals, and give structured feedback and encouragement.^{24,25} Our participants were able to see their step count each day, but we did not provide tools to monitor longitudinal progress. The decline in adherence we observed indicates that while participants were open to using the devices, further research is necessary to determine how best to encourage continued adherence. One potential strategy would be to utilize a wrist worn model of FitBit, which might be less easily removed or forgotten than the waist-worn model selected for this study.

In the absence of specific guidance about scale use, the sustained use of the devices (on average >once/week) over the intervention period indicated acceptability. Regular self-weighing is associated with weight loss, with some weight loss interventions recommending daily self-weighing.⁹ Weighing once a week, which most participants in this study did would have been sufficient for them to observe the overall trend in their weight if they were to continue this behavior over a longer intervention period, which is the aim of the self-weighing approach. That there was no significant difference in use between the two groups that used the scales indicates that additional feedback about physical activity from the FitBit did not significantly affect the frequency of self-weighing.

Psychosocial Indicators of Health

Individuals with a higher internal locus of control have been identified as more likely to engage in health promoting behaviors.²⁶ The fact that participants in this study increased their scores on all three of the HLOC subscales suggests that they felt simultaneously more in control of their

own health, but were also more aware of the influence of outside forces, including chance and other people. This may have been as a result of setting goals for themselves that could not be met because of outside obligations. Self-efficacy has also been identified as essential for helping individuals who intend to make health behavior changes to follow through with action.²⁷ Despite the lack of association with behavior change, the significant increase in Self-Efficacy for Exercise and Weight Efficacy among all of the participants in this study is encouraging.^{21,22} Whether improved self-efficacy can be directly attributed to the devices and their feedback rather than simply enrolling in a trial with a focus on physical activity/health should be the subject of future research. Several prior intervention studies have observed improved physical activity in those with higher self-efficacy at baseline, but few have attempted to measure the opposite phenomenon.^{27,28}

The psychological impact of weight-focused interventions has been broadly discussed, extensively in the Pacific context, but to date few studies have intentionally measured the effect of any given intervention on self-reported health and quality of life.²⁹ Here, we found mixed, and somewhat contradictory results: in the group who received only the FitBit, quality of life related to health (both physical and mental) worsened, but self-reported health status improved. We did learn, however, in post-hoc analyses that the decline in quality of life may have been driven by those participants who lost or stopped wearing the devices during the intervention period. Participants may have stopped wearing the devices because they were disappointed in their activity levels or felt unable to make improvements, or may have been frustrated at the missed opportunity for feedback if the device was lost. If these individuals were excluded, there was no significant change in quality of life among this group.

Self-monitoring of weight has been identified as a “double-edged sword”; it is an effective tool for interventions, but can also worsen body image concerns in a way that might undermine progress.³⁰ In this study, both groups that received a scale were less likely to report “excellent” self-reported health post-intervention than at baseline. Given that both groups gained a significant amount of weight during the intervention period, and that public health messaging about the impact of weight on health is widespread, this may simply reflect acknowledgement of their weight status and their level of risk for additional, related conditions. But, we did not explore participants’

conceptions of health holistically enough to be sure that there were not negative consequences for body image. This should be fully explored in later studies.

Limitations

While the introduction of these devices to the Samoan setting was innovative and the findings suggest many avenues for future study, they must be considered in the context of several limitations. The small sample size and large degree of variability in the sample limited the power of analyses to identify a clear pattern in behavior, if one existed. The analyses were also limited by a significant decline in adherence to device use and our inability to differentiate a decline in adherence from a decline in physical activity. Using 100 steps as the cutoff to establish a day of device wear was a reasoned decision, but there was little evidence available on which to base this choice. Future studies could address these limitations by using a wrist worn model of FitBit that included heart rate tracking to better establish participant use and incentives for continued adherence. Additionally, while we believe participants were compliant with the use of tape to mask the step count display, this method was imperfect and could be improved.

This study was designed as a pre/post comparison, with individual behaviors during the intervention period compared to the individual’s baseline values. While there is no evidence to suggest that there was a population wide change during this relatively short study period, the lack of a control group is another potential limitation of this design. As a feasibility study, the included intervention was not framed around specific physical activity or weight loss goals. This approach was taken to explore how participants in this setting used these devices in the absence of other guidance. However, the lack of a change in step counts may be in part the result of this approach. Finally, although the FitBit and BodyTrace® devices we chose here would still be relatively expensive for the Samoan population, costing \$60-80 USD compared to the average weekly household income of approximately \$260, participants could obtain similar feedback from less expensive devices without the web-based platform.³¹

CONCLUSIONS

Given the expanding access to mobile technologies in the Pacific, this is an ideal moment to introduce self-monitoring

technologies as a potential tool to address the rising burden of obesity and NCDs. The increase in BMI that occurred over the relatively short study period reinforces the need for weight control interventions in this setting. The results of this study suggest that FitBit step counters (or their less expensive equivalent) and weighing scales may be an acceptable and potentially effective tool for interventions to utilize in the Samoan setting. While no significant difference was observed in participant's physical activity, improvements to psychosocial indicators of health suggest a positive effect of using these devices, although further research is needed to determine how to sustain device usage over time, and to evaluate the effect of these devices on physical activity and weight in a more structured intervention approach.

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Competing interests: The authors declare that they have no competing interests.

Author contribution list: ELK and NLH conceived the study and prepared the study protocol and approvals. TN provided oversight of the project and facilitated research approvals in Samoa. ELK and ACR completed data collection. ELK conducted data analysis in collaboration with NLH and MMD. ELK prepared the manuscript for submission. All authors reviewed, revised, and approved the final manuscript.

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