

Protocol

Study Title: Using Social Connectedness to Increase Physical Activity

Identifier: NCT04573972

Unique Protocol ID: STUDY2019_00000296

Date: October 22, 2021

Hypotheses

Hypotheses are pre-registered at ClinicalTrials.gov NCT04573972

<https://clinicaltrials.gov/ct2/show/NCT04573972>

We hypothesize that, compared to the regular incentive condition, participants in the social incentive condition will show a larger positive change in daily steps walked during the baseline period to daily steps walked in the post-intervention period.

Study Design

Participants volunteered for the study with a friend; thus randomization occurs at the level of the dyad, with half the dyads assigned to the regular incentive condition and half to the social incentive condition. During a 5-week protocol, participants complete a 1-week baseline period, a 2-week incentive period and a 2-week post-incentive period.

Communication with participants occurred using the Way to Health (W2H) platform. Participants downloaded the FitBit and Aware apps onto their IOS or Android smart phone to track steps walked and GPS location. They completed surveys on W2H at the beginning and end of the survey. W2H sent participants text messages each morning and evening. During the baseline period participants earned \$1 for each day they synced both apps. After the baseline period all participants were assigned a daily step goal that represented a 30% increase in daily steps walked. During the incentive and post-incentive periods, the evening text message included a link to a survey where participants could self-report walking with their partner. During both of these periods, participants earned \$1 per day for syncing the apps and an additional \$1 per day for completing the evening survey. During the incentive period only, they earn \$2 per day for meeting their step goal (regular incentive) or they earn \$1 per day for meeting their step goal and an additional \$1 per day for walking at least 1 mile with their partner. At the completion of the study, participants were mailed a ClinCard debit card loaded with their payment total.

Randomization

Simple randomization to condition was accomplished via the W2H platform at the completion of the baseline period. Because W2H does not have the capacity to randomize at the level of the dyad, the research team manually adjusted conditions such that both members of a dyad were in the same study condition.

Data collection procedures

Study participants were recruited at Carnegie Mellon University through posting on the subject pool website and announcements to undergraduate classes. Potential participants had to sign up with a friend, with at least one member of the friend pair being a current CMU student. Participants had to own an IOS or Android smartphone and be willing to download the FITBit and Aware apps to track their activity and location for 5 weeks.

Stopping rule

Our stopping rule was to close enrollment once 220 people were fully enrolled or when Oct 15, 2020 occurs, whichever comes first. We opened enrollment on Oct 1, 2020 and closed it on Oct 11, 2020 because at that point 220 people had fully enrolled. Fully enrolling includes consenting, completing the intake survey, providing a code for a partner who was also enrolling, and downloading the FitBit and Aware apps. Some of the individuals who fully enrolled were not included in the study because their partner did not fully enroll.

Manipulated variables

There was one manipulated variable (treatment condition) with two levels: regular vs. social incentive.

Measured variables

Primary dependent variables (as pre-registered on Clinical Trials)

1. The mean daily treatment period step count (averaged across all of a participant's included treatment period days) minus the mean daily baseline period step count (averaged across all of a participant's included baseline period days).
2. The mean daily followup period step count (averaged across all of a participant's included followup period days) minus the mean daily baseline period step count (averaged across all of a participant's included baseline period days).
3. Number of days during treatment period when participant reached goal. Converted to a fraction by dividing by the number of included treatment period days.

4. Number of days during followup period when participant reached goal. Converted to a fraction by dividing by the number of included followup period days.
5. Change in score on UCLA Loneliness Scale. Score on post-test (range 0 to 60) minus score on pretest.

Secondary dependent variables (as pre-registered on Clinical Trials)

6. Number of days participant walked together with partner during treatment period, as assessed via self-report on daily survey
7. Number of days participant walked together with partner during followup period, as assessed via self-report on daily survey
8. Number of days participant walked together with partner during treatment period, as assessed via Aware data
9. Number of days participant walked together with partner during followup period, as assessed via Aware data

Indices

The UCLA Loneliness Scale is measured on both the intake and exit surveys. It consists of 20 items, each scored as 0, 1, 2, or 3. The scores from all 20 items are added to form a total score ranging from 0 to 60.

Inclusion Criteria

In order to be included in the study, each participant must fulfill all of the following

- Consent
- Fully enroll, including authorizing FitBit app and installing Aware app
- Link to a friend who fully enrolls in the study before the registration deadline
- Participants who request to unenroll are excluded.
- Provide synced step data for at least one day of the 7-day baseline period
 - That is, there must be at least one baseline day with a non-zero step count
- Provide Aware data for at least one day of the 7-day baseline period

Exclusion of individual data points

- Days that a participant has a value of 0 for steps walked will be considered missing data (assume there was no sync for that day)
- For each participant, we will compute the mean and standard deviation of number of daily steps, computed over all days of the study with non-zero step counts. Days with a step count that are > 3 standard deviations away from the participant's own mean will be excluded from analyses (treated as missing data).

- Average step count will then be computed for each phase, after treating these excluded data points as missing.

Missing data

When a participant is missing step data for an individual day, the mean daily step count for the study phase will be computed using the days with non-missing data. If a participant is missing step data for all the days in a study phase, the mean daily step count for the baseline period will be substituted (leading to a change score of 0).

If a participant is missing data from the intake survey (e.g., gender, age, or UCLA loneliness score), the study-wide mean or mode will be substituted. If a participant is missing data from the exit survey (e.g, UCLA loneliness score), the corresponding value from the intake survey will be substituted.