Analysis Plan

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 way 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.

Explanation of existing data

The study protocol was pre-registered at ClinicalTrials.gov NCT04573972 https://clinicaltrials.gov/ct2/show/NCT04573972 prior to any data collection. Clinical Trials pre-registrations do not include analysis plans. Consequently, this OSF pre-registration, including an analysis plan, was filed prior to downloading any data from W2H.

Participant flow diagram: (Ben or Sommer, please fill in numbers)

XXX people entered W2H portal	→ XX did not consent
↓ XX consented	→ XX did not fully enroll
↓ XX fully enrolled	→ XX not linked to a fully-enrolled partner
↓ XX has fully-enrolled partner	→ XX did not provide synced FitBit & Aware data for at least 1 out of 7 days of pre-intervention period or has partner who did not provide synced data for 1 out of 7 pre-intervention days
↓ XX provides baseline data	→ XX requested to be unenrolled prior to randomization
↓ XX included in study and radomized to condition (N= XX/2 pairs)	
↓ XX in the regular incentive condition & YY in the social incentive 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 study. 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.

Data File Structure
- Note: remove the research team participants from the datafile.
- Daily file (35 rows per participant -- one row per day of the protocol)
    - Subject id
    - Dyad id (links together the two subject ids in a friend pair)

- - ○ Phase (baseline, incentive, followup)
    - ○ Day of protocol (1 - 35)
    - ○ Calendar date
    - ○ FitBit steps walked
    - ○ Met goal (yes or no; missing for baseline period)
    - ○ Synced FitBit data (yes or no)
    - ○ Synced Aware data (yes or no)
    - ○ Correct end-of-day survey sent (yes or no; missing for baseline period)
    - ○ Answered end-of-day survey (yes or no; missing for baseline period)
    - ○ Walked with partner (yes or no; missing if wrong survey sent or survey not answered)
    - ○ Walked at least 2,000 steps with partner (yes, no, or missing)
    - ○ Walked in-person or virtually with partner
  - Study file (1 row per participant)
    - ○ Subject id
    - ○ Included in study (for ITT analysis)
    - ○ Included in main analysis
    - ○ Dyad id (links together the two subject ids in a friend pair)
    - ○ Date started baseline period
    - ○ Date started incentive period
    - ○ Goal number of steps
    - ○ Total amount earned during study
    - ○ All responses from baseline survey
    - ○ All responses from exit survey

ITT analysis

- Includes all Ss who meet the inclusion criteria, even if they have a lot of missing data.
- Similar to the main analysis described below, but it doesn't exclude Ss based on missing data.
- It does still exclude individual data points, same as in the Main Analysis

Main Analysis

In order to be included in the main analyses, each participant must also fulfill all of the following
- Provide synced step data for at least 2 days of the 7-day baseline period
- Provide synced step data for at least 4 days of the 14-day treatment period
- Provide synced step data for at least 4 days of the 14-day followup period
- Be paired with a partner who is also also included in the main analyses

Secondary Analyses

- Secondary analyses will explore the relationships among change in UCLA Loneliness score (intake to exit survey), change in meal daily steps walked from baseline to post-incentive period, and percentage of days during post-incentive period when the dyad walked together. Specifically, we will test whether the effect of study condition on change in steps walked is mediated by change in loneliness score and percentage of days when the dyad walked together.
- Two boot-strapped mediation analyses will be conducted, one for each putative mediator.

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 (rance 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

Main Analysis
- DV = each of the primary dependent variables shown above
- IV = condition (regular vs. social incentive)
- Data structure: 1 rows of data per participant
- Errors clustered at the dyad level
- Covariates:
  - Partners in same or different time zone (dyad level)
  - Gender, age (individual level)
  - Date of first day of baseline (individual level)
  - Lag in number of days between enrollment of first partner and enrollment of second partner (dyad level)

Exploratory HLM Analysis
- DV = daily step count
- IV
  - Fixed effect of participant
  - Dummy variable for treatment period (relative to baseline period as reference)
  - Dummy variable for followup period (relative to baseline period as reference)
  - Interaction between each dummy & condition (regular vs. social incentive)

- Data structure: 35 rows of data per participant (one for each day)
- Clustering: days nested within participant; participant nested within dyad

Transformations

None planned.

Inference criteria

Alpha is set at .05

Data exclusion

See analysis plan

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.