STUDY ID: NCT02779491.

EVALUATION OF A 5-A-DAY FRUIT AND VEGETABLE MOBILE PHONE APPLICATION

STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

DOCUMENT DATE: 15.04.19

METHODS

Evaluation of the app was undertaken using a randomized controlled pilot trial, where volunteers were randomized to receive or not receive the app for either two weeks or four weeks and FV knowledge, FV intake and FV behaviour were assessed and compared at baseline and at study end.

Volunteers

Volunteers to test the app were recruited from the staff and students of Bournemouth University, UK, from Nov., 2015 to March, 2017. We aimed to recruit 100 volunteers - 50 to test the app and 50 to act as controls. No earlier research was available to allow power calculations, thus 50 volunteers were considered sufficient to gain feedback and assess potential impacts of the app, while remaining manageable should few impacts be found. Adult volunteers (aged 18 years and over) were required to own an Android smart phone, as the app was only developed for Android platforms, but there were no other inclusion / exclusion criteria to maximise the generalisability of the study. Volunteers were recruited for a study to 'test a novel mobile phone app for encouraging healthy behaviours'. Volunteers were thus aware at the study start, that they may or may not receive an app to test, but they were informed that that the app may target one of a number of health behaviours, such as exercising, stress reduction or healthy eating.

Intervention / Control

Volunteers were randomized to receive the app (intervention) or not receive the app (control). Randomization was undertaken on study entry by drawing lots, and recruitment stopped once 50 individuals had been randomized to test the app. All volunteers who received the app were asked to download the app onto their phones, to register with the app to set-up a user profile, and to use the app as often as they wished for either a two week or a four week period. The app was tested for two weeks from Nov. 2015 - March 2016 and from Nov. 2016 - March 2017, and for four weeks from June 2016 - August 2016.

Outcomes

Awareness of the 5-a-day FV recommendations, FV knowledge and FV intake were assessed as outcomes, at baseline, at a mid point, and at study end. Awareness of the recommendations, FV knowledge and self-reported FV intakes were assessed using a questionnaire previously developed by ourselves [1]. The questionnaire consisted of two questions on awareness of the 5-a-day message, four questions on knowledge of the details of the message (which foods are included, portion sizes, the need for variety, reasons for consumption), and two questions on FV intake, as

detailed below. FV behaviour was also assessed as part of the trial using a behavioural measure. Two questions on demographic and lifestyle characteristics that have previously been associated with FV consumption and dietary knowledge [1-9] were also assessed as potential confounders. All volunteers (intervention and control) completed all outcome assessments in the same manner.

Awareness of the recommendations: Awareness of the recommendations were assessed using two open-response questions: 'Are you aware of the 5-a-day FV message?' and 'What do you think it means?'

FV knowledge: FV knowledge was assessed using four structured closed-response questions on: 1) the FV that are included in the message; 2) the portion sizes that are required for the message; 3) the variety that is required for the message; and 4) the reasons for FV consumption. These questions include 1) a number of foods; 2) a number of different portions of FV; 3) a number of combinations of FV to be consumed in a day; and 4) a number of different health conditions, respectively, and respondents were asked to report 1) inclusion in the recommendations or not; 2) contribution to the recommendations based on portion sizes; 3) number of FV portions consumed in the day; and 4) impact of FV on each health condition, respectively. For all questions, a correct response, based on current recommendations from the UK Government [10], was scored +1, an incorrect response was scored -1, and 'don't know / not sure' was scored 0. Missing values were also completed with 0, where found.

Self-report FV intake: FV intake was assessed using one open-response structured question requesting household amounts (e.g. tablespoons) of all FV consumed at various time points (before breakfast, breakfast, morning, lunch, afternoon, evening meal, evening) on a typical weekday and on a typical weekend day, and one open-response question asking for estimated number of portions of FV consumed per day. The structured question was used to calculate portions of FV consumed per day (calculated FV), while the single question was used to provide an estimated measure (estimated FV).

FV Behaviour: FV intake was also assessed using a behavioural measure. Volunteers were offered a drink while completing all questionnaires, and given the choice of a tea, coffee, water or fruit smoothie. Selections of the fruit smoothie were considered an FV choice, while all other drinks were considered a non-FV choice. No drink was also a permitted option.

Demographic and Lifestyle Characteristics: Demographic and lifestyle characteristics also assessed were: gender, age, marital status, living status, number of years of education, smoking habits, alcoholic drinking habits, dietary supplement taking habits, and height and weight (to calculate BMI).

App Feedback

Number of uses were requested from volunteers who received the app, and downloaded from the app itself. Volunteers who received the app were also asked to feedback on their experiences and offer suggestions for the app.

Psychological Stress

To encourage a perception that healthy eating was not necessarily the focus of the study, the Psychological Stress Measure [11] was also provided to participants. This questionnaire consists of 49 statements relating to somatic, cognitive-affective and behavioural outcomes of stress. Respondents rate the extent to which they have experienced these outcomes in the last week on an 8-point scale ranging from 1 (not at all) to 8 (extremely). These data were not analysed.

Procedure

Volunteers undertook all outcome assessments at the Eating Behaviours Laboratory, Bournemouth University, UK. On each assessment occasion, volunteers completed all questionnaires, were offered a drink, and had every opportunity to ask questions. One researcher randomized all volunteers and dealt with all queries (IB, HP, PN, CB), while another researcher oversaw all outcome assessments, thus this researcher was blind to treatment (IB, HP, PN, CB).

The study was given ethical approval by the Research Ethics Committee of Bournemouth University, prior to commencement, and was registered as a clinical trial on www.clinicaltrials.gov (ID NCT02779491). Methods were undertaken as detailed in the trial registration with the exception that a behavioural measure of FV intake was added to the study prior to commencement, and a measure of FV attitudes was not undertaken. Attitudes towards FV were not measured to reduce demand characteristics given the extensive FV knowledge questionnaire. All participants provided written informed prior to starting the study.

Analysis: Data were analysed on an Intention-to-Treat basis, where missing data were completed using Last Observation Carried Forward. Demographic and lifestyle variables and all measures at baseline were first described and compared using t-tests, based on study duration and app / control

grouping. Several important differences were found between those studied for two weeks and those studied for four weeks, thus study duration was included in all subsequent analyses. All FV knowledge and intake outcome assessed by questionnaire were analysed using 2 (study duration) x 2 (app / control) x 2 (baseline / study end) mixed ANOVA. Our behavioural measure of FV intake – choice of fruit drink or non-fruit drink was analysed using Chi-squared tests. All data are reported as means and standard deviations. Significance was set at $p<0.05$.

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