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# An efficacy trial of 'Steps to Your Health', a health promotion programme for adults with intellectual disability

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## Abstract

**Objective—**Although there are evaluation and effectiveness studies of health promotion interventions for adults with intellectual disabilities (ID), randomized efficacy trials of such interventions are lacking.

**Design—**A randomized active control intervention trial.

**Setting—**The participants attended the health promotion classes in local disability agency service facilities. Method: We enrolled 443 individuals and randomly assigned them to one of two eight-week participatory classes. The 'Steps to Your Health' (STYH) classes emphasized moderate to vigorous physical activity (MVPA), healthy eating and body mass index (BMI) reduction. The control intervention focused on hygiene and safety.

**Results—**We did not find a statistically significant difference in mean MVPA or BMI change between completers of the STYH group compared to the control group one year after the intervention was completed. We did find that participation in STYH classes had a non-significant association with odds of reduction in BMI (odds ratio [OR] 2.87, 95% confidence interval [CI] 0.91–9.11) and completers who lived in group homes were more likely than their counterparts who lived with families or in apartments to decrease their BMI (OR 4.61; 95% CI 1.14–18.64).

**Conclusions—**This trial did not demonstrate a significant effect of STYH participation on change in mean minutes of MVPA or mean BMI 12 months after classes ended, although there was a non-significant association with odds of reduction of BMI ($p = 0.07$). This study has implications for design of intervention studies in people with intellectual disability (ID).

### Keywords

mental retardation; obesity; randomized intervention trial



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## Introduction

We designed an efficacy trial of the 'Steps to Your Health' (STYH) health promotion programme that was developed for individuals with intellectual disability (ID). STYH is an eight-session health promotion intervention that uses participatory model and social-cognitive approaches to learning to improve physical activity, limit weight gain, and reduce stress in individuals with ID.

## Background and literature review

Physical inactivity, poor nutrition, and obesity are significant challenges among people with ID.[1–7] Approximately half of community-dwelling adults with ID reported little or no leisure time physical activity,[8] and most adults with ID who lived in a group setting in the community failed to achieve sufficient physical activity for health benefits, as measured by a pedometer.[9]

Poor diet and inactivity contribute to the epidemic of obesity, which is at least as prevalent among people with ID as in the general population.[3, 10–14] The 1997–2000 National Health Interview Survey data for United States (US) community-dwelling adults with ID show 34.6% of adults were obese and 28.9% were overweight, compared with 20.6% and 34.1% respectively for adults without ID.[13] Despite the documented problems of obesity and inactivity in people with ID, there is a lack of proven interventions for this group.

The conceptual model for the development of STYH (Figure 1) was based on the social cognitive theory of health behaviour change and an understanding of the social milieu in which people with ID live.[15] The investigators previously conducted two related research projects. The first was an effectiveness study of the eight-week Health Education Learning Program (HELP) designed for normal learners. We evaluated the effectiveness of HELP with normal learners and learners with ID and found that 18.5% of those with ID and 44.3% of the normal learners lost at least 0.75 body mass index (BMI) units following participation in the eight-week programme.[16] After the completion of the HELP study the principal investigator collaborated with the author of HELP to develop the STYH curriculum, which is a modification of HELP that incorporates the concrete kinesthetic learning style of adults with ID. We piloted STYH using hundreds of individuals with ID, and wrote and tested numerous iterations of the curriculum when the learners had trouble with concepts or had difficulty with the methods. After developing the final version of STYH we conducted a second effectiveness study which evaluated 192 overweight and obese adults with ID who participated in the eight-week STYH intervention. In this study 50 people (26%) lost at least 0.8 BMI units in the eight-week program.[17] We felt a carefully controlled study was needed to carry out objective measurement of physical activity and BMI to assess the efficacy of a health promotion programme for adults with ID.

This study is a randomized control trial of STYH to test the efficacy of the intervention to prevent increase in BMI and to increase physical activity in approximately 400 community-dwelling adults with ID who were recruited through county disability agencies. The hypotheses were: (1) participants randomized to the STYH intervention will increase their moderate to vigorous physical activity (MVPA) and controls would not increase their

MVPA; and (2) participants randomized to the STYH intervention will have no increase in BMI, and controls will increase their BMI over 12 months of follow-up. We conceptualized our outcomes would be achieved through increased knowledge, change in exercise, decreased stress and improved eating practices, as well as factors we did not address in STYH (such as support; self-efficacy; personality; individual history; and environment, demographic and health characteristics).

## Method

### Participant recruitment

Participants were recruited through a network of 21 community disability and special needs (DSN) boards and other local disability agencies: 19 from South Carolina; one from Charlotte, North Carolina; and one from Augusta, Georgia. South Carolina DSN boards provide residential and day services, including supported employment and family support services to over 17,000 individuals with ID and their families. Services and supports are provided based on individual preferences and availability of a continuum of options for type of residence, day programmes, and family assistance. DSN staff members asked community-dwelling individuals living in both independent and supervised settings if they were interested in participating in a health education programme. Individuals were eligible for participation if they were between 18 and 65 years of age, had mild to moderate ID, were ambulatory, able to communicate verbally, and able to give informed consent.

### Informed consent

The study was approved by the institutional review board at the University of South Carolina. Recruitment staff contacted individuals identified through DSN staff and screened the potential participants for eligibility. Individuals' ability to participate in and learn simple concepts from a health behaviour programme was assessed using the short portable mental status questionnaire (SPMSQ). The SPMSQ was developed to be a brief, clinically useful assessment tool for assessing cognitive function and consists of 10 questions that assess the individual's orientation, memory and cognitive function.[18] Individuals were eligible if they were able to correctly answer 4 of 10 questions. Individuals who were underweight (BMI < 18.5) and those with serious medical conditions or conditions that limited participation in physical activity were excluded.

The informed consent process consisted of a recruiter informing interested individuals of the purpose and methods of the study, reading the informed consent documents to them, and providing an opportunity to ask questions and consult with family and friends before obtaining signed informed consent. When participants had a legal guardian, the recruiter worked with the disability agency staff to inform the guardian and obtain their informed consent for participation of the individual with ID.

### Randomization

The 443 participants were assigned to STYH or the control group based on random assignment. The recruitment staff identified participants who lived in the same household and only the first one enrolled was randomized as an official study participant, in either the

STYH or the control group. The other household member(s) participated in the intervention but were not included in the analysis. STYH intervention participants were divided into 14 groups, consisting of 10–15 participants. Control group participants were also divided into 14 groups, consisting of 10–15 participants.

### 'Steps to Your Health' (STYH) intervention group

The STYH intervention consisted of eight sessions, each focused on a target issue, and class participation included discussion, practice time, group activities, and healthy snacks for the participants. Transportation was provided and sessions were held in a room provided by the disability service agency in the local area where the participants lived.

The beginning of each session was used to summarize and discuss the previous lesson, answer questions, and bring up successes and problems. The sessions were organized around the following topics during the eight weeks:

- Lesson 1 Nutrition I (emphasis on fruits and vegetables)
- Lesson 2 Nutrition II (emphasis on whole grains and portion size)
- Lesson 3 Exercise
- Lesson 4 Stress management
- Lesson 5 Changing your way of thinking
- Lesson 6 Communication styles (asserting preferences)
- Lesson 7 Complications of obesity
- Lesson 8 Behaviour management

The sessions were led by a health educator who had experience working with adults with ID and understood the kinesthetic learning style of the participants. Her vocabulary and the learning materials were concrete, and every lesson was infused with examples and exercises. The sessions were 90 minutes in length and were followed by an optional brisk walk. The spacing of the sessions, at one-week intervals, was the desired frequency stated by participants who assisted with the design of the intervention.

### The control group: Hygiene and safety classes

Participants who were randomized into the control group also had transportation provided and they participated in weekly 90-minute sessions for eight weeks. The classes were designed to cover content that was not included in the STYH curriculum. The topics covered were:

- Lesson 1 Hygiene and grooming
- Lesson 2 Dental care
- Lesson 3 Physical health and check ups
- Lesson 4 Avoiding hazards and preventing accidents
- Lesson 5 Avoiding hazards and preventing accidents

- Lesson 6 Environmental health
- Lesson 7 Managing money
- Lesson 8 Managing money

All of the hygiene and safety classes included participatory activities and were considered an active control group since both these hygiene/safety classes and the STYH classes allowed for participation in a programme with peers. The control groups were run at the same time and the same location as the STYH classes.

## Measurement and data collection

The evaluator collected information on severity of ID, living situation, age, sex and race at enrolment with assistance of local agency staff. Four data collection sessions were scheduled for each participant: baseline, after completion of the intervention at nine weeks, six months and 12 months. During each evaluation session weight was measured to the nearest 0.5 kg with participants dressed in lightweight clothing without shoes using a Seca 880 model scale, and height was measured to the nearest 0.5 centimetre using a portable Shorr height-board. All measurements were taken in duplicate, if the first and second weight or height measurement differed by more than 1 kg or 1 cm, respectively, the measurements were repeated. BMI ($kg/m^2$) was calculated from the mean height and weight recorded.

Next the evaluator verbally administered questionnaires to assess knowledge and stress. Knowledge was assessed using 18 true/false questions about diet, exercise, healthy weight, and stress. A percentage correct was calculated. stress was assessed using the life stress inventory which included 30 items that describe potentially stressful events to determine if they occurred in the past few weeks. Each time a respondent reported an event had occurred there was a follow-up question as to whether this caused stress. There were two scores for the life stress inventory, one for the percentage of events experienced in recent weeks and the second score for the proportion that caused stress.

At the end of the evaluation session Actigraph accelerometers (Actigraph Inc, Shalimar, FL) were distributed and individual instruction was provided. Participants were asked to wear the accelerometer around their waist daily when awake for at least five days, including two weekend days. The family member or the staff person who brought the participant to the evaluation session was also instructed on the need for daily wear.

The evaluator conducted a home visit 7–10 days later to collect each participant's accelerometer and complete the food availability assessment, since food availability was considered a covariate in the model of BMI. The food availability assessment was accomplished by direct observation of food (availability of fruits, vegetables, grains, high fat foods, sweetened beverages and snacks, and low fat/reduced calorie foods) in the cabinets, refrigerator, and pantry of participants' homes using the STYH home food environment instrument.[19–20] This instrument was derived from the fruit and vegetable availability and the low and reduced fat foods availability questionnaires used in the girls' health enrichment multi-sites studies (GEMS) trial.[21] We combined the two tools, added some additional food items, and converted the instrument to a checklist of the types of foods available in

participants' cabinets, refrigerators and pantries. This instrument did not quantify the number of servings available; thus we determined the number of different types of fruits available but not the number of pieces/servings.

### Statistical analysis

To objectively evaluate the outcomes of increased MVPA we obtained accelerometer data using software provided by MTI and used modified Freedson cut-points (≥ 3 METS)[22, 23] to determine minutes of sedentary, light, moderate, and vigorous physical activity. Non-wear time was defined as 20 consecutive minutes with no counts.[24] We accomplished data reduction using software modified from the ACT trial.[25]

We used logistic regression (Proc LOGISTIC) and linear regression (Proc GLM) in SAS™ v9.0 (SAS Corp, Cary, NC) to test our hypotheses. The primary hypothesis was that participants randomized to the STYH intervention would increase their MVPA compared with controls over 12 months of follow-up. In the logistic regression model for analyzing the change in MVPA, we defined the outcome 'event' as having an increase in MVPA over the 12 months of follow-up. The second hypothesis was that participants randomized to the STYH intervention would not increase in BMI compared to an increase in BMI among controls over 12 months of follow-up. In the logistic regression model for analyzing the change in BMI, we defined the outcome 'event' as having a no increase of the BMI over the 12 months of follow-up.

The independent variables included in the full model were: group (STYH vs. control); age; sex; race; education; living status (group housing vs. non-group housing); total knowledge score (combined for diet, exercise, and weight control); and food availability for fruits, high fats, and low fats. For the model predicting BMI, we included MVPA as an independent variable. For the model predicting MVPA, we included BMI. We created a rate using the number of minutes of MVPA during wear-time for our measurement of MVPA.[26, 27] We calculated BMI from height and weight measurements and then did both linear and logistic modelling.

## Results

The recruitment and retention flow for the 443 participants in STYH are shown in Figure 1.

Table 1a shows baseline demographic and anthropometric characteristics and some of the participants' responses. The mean age of the study group was almost 39 years (range 19–65) and the mean BMI was 32.5 (range 18.5–71.3) at enrolment. Forty nine per cent were male and more than half of the participants were black. In terms of residence, over 40% resided in group homes, almost 50% resided with family members, and a small number resided in their own apartments or in supervised apartments. Table 1b displays the baseline findings from the knowledge questionnaire and the life stress survey. Participants correctly answered 68% of the knowledge questions about healthy diet, 64% of the questions about physical activity, and 63% of the questions about weight control. The responses to the life stress survey were positive for 24.8% of situations described, and of these challenges, the participants reported that 53.4% resulted in high levels of stress. Finally the food availability score was a count of

the number of items in the fruit (average 9.9), low fat (average 2.6) and high fat (average 4.9) group. This number is simply a count of the number of items in the home, so it is only useful in terms of change over time.

We compared the characteristics of the participants who completed the intervention and follow-up (through 12 months) to the non-completers and found they were alike in terms of BMI, race, sex, type of residence. The completers were older (40 years versus 36.9 years).

### MVPA findings

We obtained accelerometer data for 401 (90.5%) participants at baseline. Mean wear-time was 68.1 hours over seven days, with 87.4% of this time spent sedentary, 10.6% spent in light activity, and 2.0% spent in MVPA. At baseline 16.9% of the participants accumulated the recommended minimum of 150 minutes of MVPA per week. Also at baseline physical activity was inversely related to BMI category ($p = 0.02$): participants with healthy BMIs (< 25) averaged more than twice as much physical activity (158.7 mean minutes of MVPA per week versus 88.6 mean minutes of MVPA per week) as individuals who were overweight or obese ($p = 0.002$; data not shown).

Wear time for the accelerometers decreased for the 12 month measurement so we were only able to analyze 118 participants who wore accelerometers for eight or more hours for a mean of 4.0 days at baseline and 12 months. The primary hypothesis of this study was an increase of MVPA for the STYH intervention group and no such increase in controls. Our results, shown in Table 2, found 52.5% of the STYH group and 50.9% of the control group increased their MVPA at 12 months. Likewise 47.5% of the STYH group and 49.1% of the control group decreased or did not change their MVPA rate. Thus the null hypothesis was not rejected and the MVPA was not significantly increased from baseline to one year for participants in the STYH group compared to the participants in the control group.

### BMI findings

As shown in Table 1, at baseline 21% of the STYH participants were in the normal BMI range, 20% were overweight and 59% were obese. Table 2 shows that the BMI change between the STYH group and the control group did not differ significantly, and therefore the null hypothesis was not rejected. We found that 48% of the STYH participants decreased their BMI, and 49% of the control group decreased their BMI between baseline and one year follow-up ($p = 0.84$). Mean BMI decreased slightly among participants of both the STYH and control groups, but there was not a significant difference in the mean BMI change of STYH participants versus controls.

### Prediction models for increase in MVPA and decrease in BMI

We modelled predictors of BMI change between baseline and follow up. We had 76 individuals with complete data and the amount of variation explained was 16.5% using linear regression, but the overall model was not significant ($p = 0.25$; data not shown). We also used logistic regression to predict the odds of losing weight. We found that the difference between the STYH group and the control group was not statistically significant, with an odds ratio (OR) of 2.84 (95% CI [0.91–8.86], $p = 0.07$). Living in a group home was

significantly associated with increased odds of weight loss (OR = 4.57, 95% CI [1.17–17.91], $p = 0.03$), while having more low fat food available in the home setting was associated with reduced odds of weight loss (OR = 0.14, 95% CI [0.03–0.77] $p = 0.02$).

We conducted the same logistic regression using intention-to-treat modelling. We imputed values for missing variables based on the last complete entry for that variable for each individual. Thus if we were missing the 12 month knowledge, stress or food availability score, we used the six-month value, if it was available. If the six-month value was missing, we used the nine-week value, and if this was missing, we used the baseline value. As a result of this analysis, we found the only statistically significant predictor of BMI reduction to be the overall knowledge score change from baseline to 12 months (OR = 2.01, 95% CI [1.17–3.46]). Group assignment was not significant ($p = 0.28$).

## Discussion

The ‘Steps to Your Health’ efficacy trial was not successful in demonstrating that a health promotion intervention could significantly increase MVPA one year after the completion of the classes. We did find that participation in STYH classes had a non-significant association with odds of BMI reduction in the multivariable logistic regression model. The challenges that we encountered in conducting this study are noteworthy and important for future research. The main obstacle was a high drop-out rate or selective refusal to participate in aspects of the assessment during the 12-month follow-up period. The participants dropped out or failed to complete the assessments due to job-related conflicts with the class schedule or evaluation assessment, and preference to go on outings with family or disability agency staff. In addition, some participants did not want the repeat home visits to measure their food availability or to complete the questionnaires. Even among those who participated in repeated assessments, a large number of participants did not wear the accelerometers for a sufficient number of hours and days to generate reliable estimates of their personal physical activity. We believe that the $5.00 incentive at each of the four measurement times was simply not sufficient motivation for participants to adhere to the accelerometer wear time request.

In addition to conducting the efficacy trial of the STYH programme, we also collected information about knowledge, quality of life, stress, and food availability using assessment instruments that were not validated for people with ID. We did not have effect size estimates for these exploratory factors to calculate power, so our analyses of these variables were exploratory.

Our data confirm a high prevalence of obesity and inadequate levels of physical activity among community-dwelling adults with ID. Overall, at baseline 58.9% of the study population was obese compared to the general population in South Carolina (29.0% obese) or the US as a whole (26.3% obese).[28] In terms of physical activity at baseline only 16.9% of our participants met national recommendations for 150 minutes per week of MVPA or 75 minutes per week of vigorous physical activity.[29] Overall knowledge about healthy lifestyles was modest in our study population. Interestingly, exercise, diet and weight control knowledge tended to be associated with increasing BMI, so it is clear that knowledge did not

prevent overweight and obesity in this population. Perhaps adults with ID who are obese receive more education and health behaviour messages about diet, exercise, and weight control than adults with ID who are normal weight. While living in group homes was associated with higher BMIs, it was also associated with statistically significant weight loss over the one year of follow up.

In terms of study strengths this was a large study describing physical activity and BMI among community-dwelling adults with ID using objective measurement. Our study is one of only a few published studies describing objectively measured MVPA in this population and is by far the largest of those using accelerometers.[9,27,30–35]

## Conclusions

Additional studies using interventions to improve the health of this population are needed. This study used the rigorous standard of a randomized intervention trial and we did not find a statistically significant difference in MVPA between completers of the STYH intervention after 12 months of follow-up compared to the control group. We did find that adults with ID who live in group homes were more likely than their counterparts who live with families or in supervised apartments to decrease their BMI, and there was some indication from the multivariable logistic regression model that participants in STYH classes may be more inclined to lose weight, though the association did not reach statistical significance. We hope that future researchers can build on the findings of this study and work to create effective interventions for increasing physical activity and achieving healthy BMIs in adults with ID.

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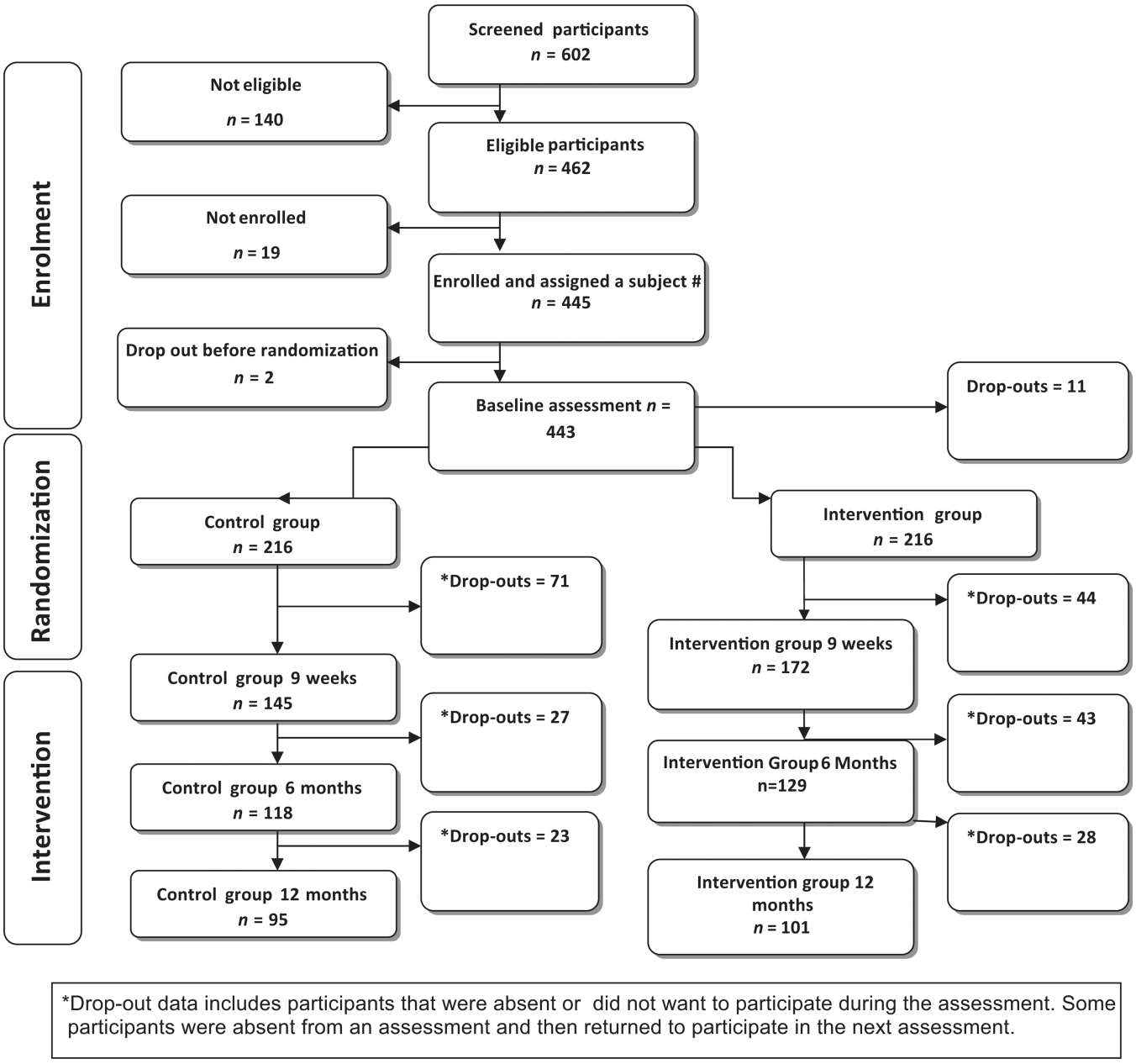


**Figure 1.**
Enrolment in STYH

## Table 1

**a. Demographic and baseline descriptors of STYH participants (*n* = 443)**

| **Demographics** | | |
|---|---|---|
| **Variable** | ***N*** | **Mean (min–max)** |
| Age (years) | 441 | 38.8 (19–70) |
| BMI (kg/m$^2$) | 437 | 32.5 (18.5–71.3) |
| | *n* | % |
| BMI | | |
| Normal < 25 | 92 | 20.8 |
| Overweight 25–30 | 87 | 19.6 |
| Obese > 30 | 261 | 58.9 |
| Missing | 3 | 0.7 |
| Sex | | |
| Male | 218 | 49.2 |
| Female | 225 | 50.3 |
| Race | | |
| White (non-Hispanic) | 185 | 41.7 |
| Black (non-Hispanic) | 252 | 56.9 |
| Hispanic | 3 | 0.7 |
| Other | 3 | 0.7 |
| Type of housing | | |
| Family | 221 | 49.9 |
| Own apartment | 16 | 3.6 |
| Supervised apartment | 21 | 4.7 |
| Group home | 183 | 41.3 |
| Missing | 2 | 0.5 |
| Years of education | | |
| Grade school | 60 | 13.5 |
| High school | 319 | 72.0 |
| Beyond high school | 3 | 0.7 |
| Don’t know | 4 | 0.9 |
| Missing | 57 | 12.9 |

**b. STYH questionnaires: knowledge, stress and food availability**

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| **Knowledge questionnaire (% Correct) (*n* = 441)** | **Average score (min–max)** |
|---|---|
| Total | 0.65 (0–1) |
| Diet section | 0.68 (0–1) |
| Exercise section | 0.64 (0–1) |

**b. STYH questionnaires: knowledge, stress and food availability**

*

| Knowledge questionnaire (% Correct) (*n* = 441) | Average score (min–max) |
|---|---|
| Weight section | 0.63 (0–1) |
| Life stress survey (*n* = 435) | |
| Section A (challenges in life) | 24.8% (0–65.3%) |
| Section B (stress from challenges) | 53.4% (0–100%) |
| Food availability (*n* = 317) | |
| Fruit | 9.92 (0–28) |
| Low fat | 2.62 (0–21) |
| High fat | 4.87 (0–16) |

* All scores exclude ‘don’t know’, ‘missing’, and ‘refused’ responses.

**Table 2**

MVPA rate* and BMI change from baseline to one year, by group assignment

| MVPA rate | STYH group (*n* = 61) | | Comparison group (*n* = 57) | | *P*-value |
|---|---|---|---|---|---|
| | Mean | (std) | Mean | (std) | |
| Baseline MV rate | 0.024 | (0.025) | 0.021 | (0.0301) | 0.564 |
| Follow-up MV rate | 0.023 | (0.025) | 0.020 | (0.0188) | 0.379 |
| Mean change | −0.001 | (0.025) | −0.002 | (0.0325) | 0.905 |
| | n | % | n | % | |
| Increase | 32 | (52.460) | 29 | (50.88) | |
| | % | | % | | *P*-value |
| MVPA rate increase from baseline to follow-up | 52.46% | | 50.88% | | 0.864 |
| MVPA rate decrease from baseline to follow-up | 47.54% | | 49.12% | | |
| BMI | STYH group (*n* = 101) | | Comparison group (*n* = 94) | | *P*-value |
| | Mean | (std) | Mean | (std) | |
| Baseline BMI | 32.3841 | (8.5563) | 33.8615 | (8.6087) | 0.231 |
| Follow-up BMI | 32.1318 | (8.5674) | 33.6367 | (8.6572) | 0.224 |
| Mean change | −0.2523 | (2.3098) | −.2248 | (2.7683) | 0.940 |
| | n | % | N | % | |
| Increase | 53 | (52.48) | 48 | (51.06) | |
| | % | | % | | *P*-value |
| BMI decrease from baseline to follow-up | 47.52% | | 48.94% | | 0.844 |
| BMI increase** from baseline to follow-up | 52.48% | | 51.06% | | |

*MVPA rate = MVPA minutes/minutes of wear time.

**One individual had the same BMI at the two measurement points.