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Protocol

A quasi-experimental study evaluating a health promotion program targeting healthy nutrition, physical activity and social network enhancement for low-income multi-problem households: study protocol

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ABSTRACT

Background: Previous studies have shown that people living in multi-problem households are less physically active, eat less healthy, have unstable social networks, and worse self-perceived general health than other people. The aim of this paper is to describe the development and evaluation of a health promotion program called "Back2Balance" for low-income multi-problem households aimed at improving healthy nutrition, physical activity, social networks, and self-perceived health.
Methods: The Back2Balance program was developed using input from two formative studies and a co-creation process together with the target group and social workers. We used the theoretical domains framework to identify the functional components of our program. The Back2Balance program consists of: 1) a walking group, 2) cooking workshops, 3) motivational talks, 4) discounts on existing health promotion programs, and 5) family trips and children's activities. In a quasi-experimental study respondents in the intervention group receive the usual social services support for multi-problem households and have the possibility to enroll in the program. Respondents in the control group only receive usual social services support. The program will be evaluated among 272 respondents from low-income multi-problem households living in Apeldoorn, the Netherlands.
Conclusions: This protocol describes the development and evaluation of the Back2Balance program. We hypothesize that the program will lead to increased physical activity, healthy nutrition, social networks enhancement, and self-perceived health. The results of this study can be used as input for other national or international initiatives aiming to increase health of low-income multi-problem households.
Trial registration: NTR6512

Keywords: Multi-problem households, Physical activity, Healthy nutrition, Social network

INTRODUCTION

People who have a low household income due to unemployment, irregular jobs, or debts often live less healthy than other people.[1-3] Besides financial problems, this group also experiences other problems, such as domestic violence, psychiatric disorders, substance abuse, or delinquency.[4-6] Multi-problem households often have unstable social networks, fewer social skills for maintaining relationships, and asymmetrical relationships

due to low reciprocity, making them prone to social isolation.[7] Research has also shown that multi-problem households are less physically active, that they eat less healthy, have higher perceived stress, and worse self-perceived health.[8-10] Due to the clustering of these unhealthy behaviors, multi-problem households are an important target group for health promotion programs. The fact that this group often gets support from social workers provides an opportunity to address and change physical activity and nutrition behaviors as well as strengthen social networks.[11]

An important prerequisite to designing interventions targeting behavior change is to understand the factors that influence the target behaviors. Our formative research identified a number of barriers for health behavior change among multi-problem households: high financial expenses for sports and healthy nutrition, low motivation to increase physical activity and to change dietary intake, incorrect knowledge about healthy nutrition, and a lack of time for physical activity.[12] The multi-problem households in our formative research had a very low socio-economic status (SES), with many of them having financial debts and receiving a weekly food bank package. Therefore, they had too many financial barriers for fun and relaxing family activities. Many also reported high levels of stress, a very small social network, lost contact with family, and poor neighbor relations. These findings are also reported in other countries (e.g. United States, United Kingdom, Australia).[13-16]

Recommendations for health promotion interventions mentioned by adults from multi-problem households were social events such as outdoor sports or playing events to increase social contacts, free or cheap health promotion activities, such as walking groups, cooking classes to learn how to cook healthy meals and socialize by eating together. Also, children's activities in nature were suggested to increase physical activity and socialize more.[12] Previous studies have investigated interventions aimed at increasing healthy nutrition and physical activity among individuals with a low SES. One systematic review and meta-analysis about physical activity programs for women with a low SES showed that physical activity interventions in group sessions increase the chance of significant effects on physical activity.[17] A literature review about cooking classes among adults also showed positive effects, although not many studies of high quality have been conducted.[18]

Despite some promising results of several interventions targeting lifestyle behaviors, to our knowledge there has been no previous trial of a broad and integrated health promotion program for multi-problem households targeting physical activity, healthy nutrition, engagement in social networks as well as self-perceived health. Self-perceived health is an important outcome for interventions targeting health behaviors, as it has been shown to be a strong predictor of mortality as well as health system utilization.[19-21] Based on the previous studies and a co-creation process together with the target group and social workers, an integrated intervention program has been developed aimed at increasing physical activity, healthy nutrition, social interaction and self-perceived health. The goal of the current paper is to give a description of the program and the quasi-experimental study that will be performed to examine the (cost-) effectiveness of the program.

METHODS

To improve the situation of low-income multi-problem households, we developed a health promotion program called "Back2Balance", targeting healthy nutrition, physical activity and social network enhancement. Two formative studies were conducted to inform the development of our program.

First, we identified main barriers for health behavior change among our target group by conducting individual interviews with adults from low-income multi-problem households and a focus group interview with social workers who provide intensive social assistance or welfare support to multi-problem households.[12] Main barriers for health behavior change were low motivation, incorrect knowledge, financial barriers and high levels of stress. Adults from multi-problem households and social workers recommended free or cheap health promotion activities, focusing on physical activity, nutrition, and social interaction. Other health behaviors, such as smoking and alcohol were regarded to be of a less high priority by them, partly due to low prevalence levels of alcohol, partly because of low motivation in the target group to change these behaviors.[12]

The second formative study was an online Delphi study to determine which preconditions regarding content and method of delivery should be taken into account when developing a health promotion intervention for people with a low SES.[22,23] Dutch experts in health behavior change among people with a low SES were asked to reach consensus about the most important preconditions for health promotion interventions for people with a low SES. The preconditions for which consensus was reached, implied that interventions should take the social environment and perceptions of the target group into account and they should involve the target group in the development. The findings showed that experts indicated that it is important that interventions have an accessible character and that intervention materials are understandable and do not use patronizing language. Finally, results revealed the importance of interventions having a large reach among the target group and that they remain available for a long period.

Based on the results of the qualitative study and taking into account the preconditions of the Delphi study, we developed our program. This was done in co-creation with the target group, and with involvement of social workers and an expert panel.

The Back2Balance program

In order to identify and clarify the functional components of our program, we use the Theoretical Domains Framework (TDF) to link barriers to effective behavior change techniques. The TDF is an integrative framework developed from a synthesis of psychological theories as a tool to identify behavior change techniques.[24] The TDF consists of 12 domains, such as knowledge, cognitive and interpersonal skills, beliefs about consequences, motivation and goals. Applying the TDF framework to our identified barriers, a total of 4 out of the 12 domains play a role in health behavior change in multi-problem households (Table 1). Therefore, we will focus on modifying 4 theoretical domains in our program.

Table 1: Behavior change techniques of the health promotion program "Back2Balance" by relevant domains of the Theoretical Domains Framework.

Barriers	TDF domain	Behavior change techniques	Intervention components
Not knowing what healthy nutrition is	Knowledge	1) Information regarding behavior and outcome	*Mode:* Cooking classes *Technique:* Education *Content:* In the cooking workshop participants will learn what a healthy meal is.
Lack of skills to cook a healthy, inexpensive meal	Cognitive and interpersonal skills	1) Specifying goal/target 2) Monitoring 3) Self-monitoring 4) Rewards/incentives 5) Graded-task: starting with easy tasks 6) Increasing skills: goal setting 7) Rehearsal of relevant skills 8) Modelling/demonstration of behavior by others. 9) Homework 10) Perform behavior in different settings	*Mode:* Cooking classes *Technique:* Modelling/demonstration of behavior by others *Content:* In the cooking class participants will learn how to cook a healthy meal.
Low motivation to increase physical activity **Low motivation to change dietary intake**	Motivations and goals	1) Specifying goal/target 2) Contract 3) Rewards/incentives 4) Graded-task: starting with easy tasks 5) Increasing skills: goal setting 6) Social processes of encouragement, pressure, support 7) Persuasive communication 8) Information regarding behavior, outcome	*Mode:* Motivational talks *Technique:* Persuasive communication, Information regarding behavior, outcome. *Content:* In a face-to-face conversation a social worker will try to increase the motivation to change health behavior and discusses how health behavior can be changed and how social networks can be strengthened.
High financial expenses for sports and healthy eating **High financial expenses for social network enhancement**	Environmental context and resources	1) Environmental changes and support	*Mode:* Discounts on existing health promotion programs; organization of free family trips and cheap children's activities. *Technique:* Environmental changes and support. *Content:* The discounts are for existing health promotion programs that focus on increasing physical exercise, healthy eating or relaxation. The family trips and children's activities will be organized according to the preferences of the participants.

The Back2Balance program aims to:

- Enhance participants' social network and increase their motivation to engage in physical activity. A weekly walking group is organized to increase participants' physical activity and to enhance their network through social processes of encouragement and social support. Due to the social cohesion of

walking groups, supportive effects may encourage physical activity and broadening of participants' social environment.[25]

- Increasing cooking skills and knowledge about healthy eating. In monthly cooking classes participants learn about healthy nutrition and learn to cook healthy meals through information provision and learning from other people how to prepare healthy, inexpensive meals (i.e. modelling). Additionally, this class also aims to strengthen the social network of participants.
- Increasing motivation for health behavior change. Motivational talks with their social worker and the activity organizer about health behavior change and social network enhancement. The motivational talks aim to increase motivation to change health behavior and to discuss how health behavior can be changed and how social networks can be strengthened. The motivational talks incorporate the following behavior change techniques: persuasive communication and information regarding behavior and outcome.
- Decreasing financial barriers for physical exercise and healthy eating. Participants are offered discounts on existing health promotion programs. The discounts aim to make the existing health promotion programs more accessible to participants in order for them to take part in these programs. The existing health promotion programs focus on increasing physical exercise, healthy eating, or relaxation. The advantage of referring participants to the existing programs is that they can continue taking part in these health promotion programs when their participation in the Back2Balance program ends.
- Decreasing financial barriers for social network enhancement. Family trips (once every three months) and children's activities (also once every three months) are organized with the aim to strengthen the social network. As in one of our preparatory studies it appeared that our target group prefers an intervention that is fun, jointly and sociable, these elements have been chosen to be part of the program. Family trips and children's activities have also been incorporated in our program to make the program attractive for potential participants.

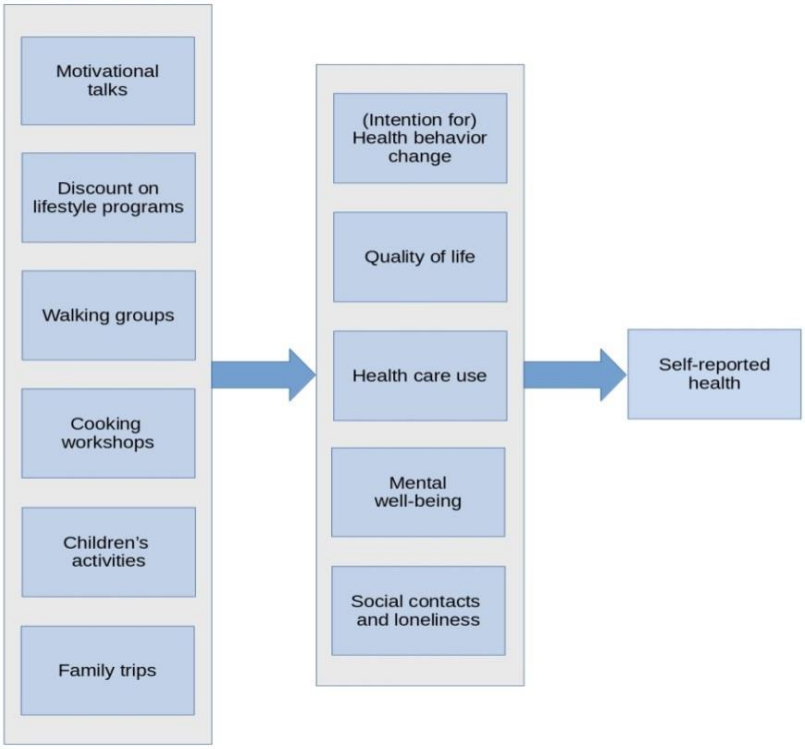

Figure 1: Conceptual model of the hypothesized program effects.

Study design

This study has a quasi-experimental design. Our program is delivered to multi-problem households living in Apeldoorn, a municipality with 160,000 inhabitants in the Netherlands. The Back2Balance program is conducted in existing meeting points of the municipality of Apeldoorn which are organized by social workers for citizens with lower income. The Back2Balance program is partly executed by social workers who work in certain city districts. For these practical reasons we have chosen to allocate city districts to either the intervention or control group instead of randomizing individual respondents. Respondents from the southern part of Apeldoorn are in the intervention group and respondents from the northern part of Apeldoorn are in the control group. Respondents

in the intervention group receive the usual social services support for multi-problem households and have the possibility to enroll in the Back2Balance program. Respondents in the control group only receive usual social services support for multi-problem households which is tailored to the specific problems of the household.[26] Outcome variables are measured with questionnaires at three time points: at baseline (T1), 6 months post-measurement (T2) and 12 month post-measurement (T3).

The south of Apeldoorn and the north of Apeldoorn are comparable regarding number of households with children, average household size, percentage of owner-occupied houses and number of households below or around the social minimum.[27] Even though the approach of social services is similar across Apeldoorn, different social workers operate in the southern regions than in the northern regions of Apeldoorn, which reduces the risk of contamination in the control group.

Procedure

The Back2Balance program is carried out by staff and interns of the welfare organization Stimenz. This study has a participatory action research approach that aims to "bring together action and reflection, theory and practice, in participation with others, in the pursuit of practical solutions to issues of pressing concern to people, and more generally the flourishing of individual persons and their communities".[28] This implies a flexible attitude of the researchers and program executers and a continuous process of listening to the target group and possibly redesigning program elements. Components of our program are therefore subject to possible change during the course of this study.

Respondents in the intervention group can follow all components of our program but they are also allowed to follow only one or a few components. Participation is not obligatory and it is also allowed to quit after following one or a few sessions. This flexible approach was recommended in one of our preparatory study.[22]

Both respondents in the intervention and control group receive filled grocery bags if they participate in the first questionnaire. All respondents age 12 to 17-year old who participate in the first questionnaire get a coupon of €10 that they can spend in a budget sports store.

Respondents

Most individuals are expected to be recruited for this study by their social worker either during a face-to-face meeting or by telephone. They assess eligibility, give potential respondents a flyer about the study, and ask them to participate. Some individuals are expected to be recruited directly by staff of Stimenz or by other professionals, such as practice nurses. Individuals are recruited only after any urgent crises situations (e.g., safety of the children at risk or an upcoming housing eviction) are solved. Respondents sign an informed consent form before taking part in the study.

Inclusion criteria

Inclusion criteria were A disposable household income up to 150% of the minimum wage; Problems in more than one of the following areas on which social workers in Apeldoorn work (eligibility for participation depends on the assessment of the social worker, staff or other professionals involved in direct recruitment): 1-social networking and social participation, 2-finances, 3-mental health, physical health, addiction and domestic relations, daycare, school, or work, housing, delinquency; 12 years of age or older; Residing in Apeldoorn or in the surrounding villages if the villages fall under the work area of the social workers in Apeldoorn.

Exclusion criteria

Exclusion criteria were Incomprehension of the Dutch language; Having an intellectual disability; Being a geriatric patient; Unwilling to fill in the informed consent form; For minors aged 12-15 years old: parents who do not want to fill in the permission form (this age range is in line with the Dutch Medical Research Act).

Sample size calculation

The sample size is based on standardized effect sizes from two meta-analyses of interventions for a similar target audience. These interventions were aimed at promoting family well-being and preventing children from being abused or from being removed from their residence. These effect sizes are d=0.41 and d=0.49, which are medium effects.[29,30] Based on an effect size of d=0.41, with 80% power and alpha of 0.05 (two-sided test), we need 95 respondents per group. Accounting for a drop-out rate of 30%, we need 272 respondents in total who enroll in our study.

Ethical approval and trial registration

The study protocol was approved by the Medical Ethics Committee of Zuyderland and Zuyd Hogeschool (METC number: 17-N-80) and the study was registered at the Dutch Trial Register (NTR6512).

Measurement instruments

Self-perceived health is the primary outcome of this study. This is measured with one question: "How is your health condition generally?", which people can indicate on a five-point scale from "very good" to "very bad".[19,31] Previous studies of single-item self-rated health measures reported high predictive validity for mortality and health care utilization, although the study populations often consisted of elderly persons.[20,32] We added smiley faces above the scale to facilitate interpretation, especially

among children and among adults with a lower than average IQ.

Secondary outcomes are: health behavior (physical activity, vegetable consumption, fruit consumption, breakfast rate, soda and juice consumption), BMI (self-reported), health care use, quality of life, social contacts, social and emotional loneliness. Physical activity is measured using the IPAQ questionnaire.[33] Vegetable, fruit and breakfast consumption are measured with questions from the Public Health Monitor.[34] These include questions about how many times a week one consumes vegetables, fruit or breakfast and a follow-up question about how much is consumed on a typical day (in serving spoons of vegetables or pieces of fruit). Soft drink and juice consumption are measured with questions from the questionnaire of the study Health Behavior in School-aged Children (HBSC). BMI is measured by asking respondents' length and weight. Health care use is measured by asking for the number of times of contact with healthcare providers, possible stays in a hospital, home care, help from family or friends, amount of days unable to perform daily activities, and use of medication.[35,36] Quality of life is measured with a standardized quality of life questionnaire, EuroQol 5-D-5-L.[37] Social contacts was measured by the following questions: "How often do you have contact with one or more family members?", "How often do you have contact with friends or acquaintances?", "How often do you have contact with neighbors or people who live in your street?". The following response options are provided: at least once a week, three times a month, two times a month, once a month, less than once a month, rarely or never.[34] Social and emotional loneliness were measured by a 6-item validated scale for overall, emotional, and social loneliness.[38]

Other variables that are measured are:

Characteristics: age, gender, household composition, marital status, work status, ethnicity, education, financial problems, and social work assistance.

Mediators: Intention to change health behavior was measured by asking "do you intend to engage in more physical activity in the next six months?", "do you intend to eat more vegetables in the next six months?", "do you intend to eat more fruits in the next six months?", "do you intend to have breakfast more often in the next six months?", "do you intend to drink less soft drinks in the next six months?", and "do you intend to drink less juice in the next six months?" Response options were provided on a 5 point Likert scale: certainly, probably, maybe, maybe not, probably not, certainly not. Mental well-being was measured using the 5-item Mental Health Inventory in which three questions assess depressive symptoms and psychological well-being, and two questions measure symptoms of anxiety.[39]

Moderator: health literacy was measured by three questions assessing problems with understanding written information, confidence filling out medical forms and how often help is needed to read medical information.[40,41]

The questionnaire for minors (12 to 15 years) contains only the primary outcome measure, the secondary outcome measures (except health care use and quality of life) and the main characteristics. The questionnaire for minors has been adapted to their level of language use.

Process evaluation

A process evaluation is conducted among participants and non-participants of the Back2Balance program in the intervention group. Primary research questions for the process evaluation are what motivates or hinders respondents in the intervention group to participate in the Back2Balance program and what motivates or hinders them to keep participating. Secondary research questions are what the reach and satisfaction of the program parts is and whether participants and non-participants have any suggestions for improvement of the program. These questions are answered with questionnaires (as part of the T1 questionnaire) and with individual in-depth interviews. In the questionnaire, questions concerning participation in the various elements of the Back2Balance program and appreciation for the various elements (only for participants in the intervention group) were asked. Additionally, a process evaluation is performed among social workers from the intervention group and the staff and interns of the welfare organization Stimenz who supervised the activities. In individual in-depth interviews, these professionals are asked to what extent they have stimulated their clients to change their health behavior, to strengthen their social network, and to participate in the Back2Balance program, and what motivated or hindered them to stimulate their clients. Also, suggestions for improvement of the program are discussed.

The individual in-depth interviews are held between three months and six months after individuals' baseline survey. When important suggestions for improvement or hindering factors for participation are found and it is possible to make improvements to the program based on these results, this will be done as soon as possible. This is in line with the principles of participative action research.[28]

Statistical analyses

All data are analyzed according to the intention-to-treat principle, which means that all data from respondents are used in the analyses whether they have filled in all follow-up surveys or not. A two-tailed test is considered statistically significant at p-values below 0.05. The primary analysis examines the difference between intervention and control group in the change in self-reported health between baseline and 12-month follow-

up. Generalized Mixed Models are used with the identity link to be able to account for repeated measures of the same individuals and nesting of individuals within households. Time, group (intervention or control) and the interaction between time and group are treated as fixed factors. Baseline characteristics of respondents such as age, gender, education, and health literacy are considered as potential effect modifiers, and will therefore be explored by moderation analyses. If there are missing values in these baseline characteristics, multiple imputation will be used. Missing data in the outcome variables are not being imputed, since the likelihood-based approach is used to deal with missing values.[42]

Secondary analyses examine the difference between intervention and control group in the change in secondary outcomes between baseline and 6 and 12-month follow-up. For these analyses, we also use Generalized Mixed Models, with the identity link for continuous outcomes and the logit link for binary outcomes. Additionally, dose-response effects and differential effects of certain parts of the Back2Balance program are explored by relating participation to changes in primary and secondary outcomes. Finally, mediation analyses will test whether the program (parts) influence outcomes by first influencing mediators, as hypothesized in our conceptual model (Figure 1). These analyses are performed with structural equation modeling.

Economic evaluation

For the cost effectiveness analyses, total costs are estimated with the micro-costing approach. We take into account intervention costs, health care costs, respondent and family costs, and costs outside health care (for example costs paid by the municipality). To this end, a cost questionnaire is developed with all relevant cost aspects for our respondents, based on existing questionnaires.[35,36] Respondents are asked to report their health care use at each measurement wave over the past six months. The effects are expressed in changes in self-reported health (primary outcome). Additionally, secondary analyses examine the cost per health behavior change.

For the cost utility analyses, effects are expressed in utilities derived from the standardized quality of life questionnaire, EuroQol 5-D-5-L, using Dutch tariff.[37] This questionnaire has five dimensions of health-related quality of life: mobility, self-care, daily activities, pain/discomfort, and depression/anxiety. Utility values are calculated from the sum of these five dimensions, using a scoring algorithm of preferences of the general population. The utilities of each measurement wave can be used to calculate a quality adjusted life years (QALY) score.

The economic evaluation is also conducted using the intention-to-treat principle. Non-parametric bootstrapping is used to determine the difference in costs between intervention group and control group. The results of the economic evaluation are presented in figures (cost-effectiveness plane and cost-effectiveness acceptability curves). The incremental cost-effectiveness ratio is determined on the basis of incremental costs and effects of the intervention compared to the control group. The cost-effectiveness ratio is stated in terms of costs per outcome, the cost-utility ratio in terms of net cost per QALY gained.

Finally, sensitivity analyses are performed to determine the robustness of the findings. In these sensitivity analyses, uncertain factors and assumptions are recalculated to examine whether these factors and assumptions have influenced the results, for example by varying the cost prices between minimum and maximum.

DISCUSSION

This protocol describes the development and evaluation of the Back2Balance program. The program consists of the following components: 1) walking groups, 2) cooking workshops, 3) motivational talks, 4) discounts on existing health promotion programs, and 5) family trips and children's activities. The aim of the study is to investigate the effectiveness of the program on physical activity, healthy nutrition, engagement in social networks and subsequently self-reported health in a sample of low-income multi-problem households in the Netherlands. In total 272 respondents from the southern part of Apeldoorn (intervention group) and from the northern part of Apeldoorn (control group) participate in this quasi-experimental study.

No studies have been conducted that investigate a broad and integrated health promotion program for multi-problem households targeting physical activity, healthy nutrition, engagement in social networks as well as self-perceived health. As single-component interventions targeting physical activity and nutrition among lower socioeconomic groups have proven to be ineffective, an integrated approach in which care providers or social services work together to increase health and enhance social functioning is recommended.[5,43]

Strengths

This study has several strengths. The Back2Balance program was developed based on two preparatory studies. The program was co-created together with target group, and with involvement of social workers and an expert panel. Our evaluation study will not only assess the effectiveness of the program, but we will also measure possible mediators of the effects, perform a process evaluation, and an economic evaluation. Mediation analyses and the process evaluation will help in understanding why and how certain effects occur and how the program can be further improved. The economic evaluation will help municipal decision making about

possible continuation of the program after this study ends.

This study has a participatory action research approach. In action research, researchers and participants collaborate on an equal basis by jointly planning, observing, reflecting and possibly redesigning program elements in order to fit the needs of the community in which the program takes place.[44] The value of action research is that it provides a powerful means of improving and enhancing practice by empowering participants to make changes in practice.[45] It also is a way to bridge the well-known research-practice gap: the gap between academic research and the engagement as well as contribution to practice.[46] Through input from the community and researchers as well as active community engagement this study aims to bridge the research-practice gap and ultimately to increase health of participants.

Limitations

An important limitation that deserves to be acknowledged is that respondents are not randomized between intervention and control group. The quasi-experimental design of the study prevents us from drawing causal conclusions about the effectiveness of the program. Respondents from the intervention and control group may differ from each other because they live in different parts of Apeldoorn or because of recruitment bias. Social workers in both the intervention and control group are asked to recruit all of their clients who fulfill the criteria, but it is likely that some social workers in the intervention group recruit only those clients whom they think will enjoy and need the Back2Balance program.

One of our formative studies showed that it is important that health promotion programs for groups with a low socioeconomic status have an accessible character.[22,23] Therefore, respondents in the intervention group can follow all components of our program but they are also allowed to follow none or only one component. This flexibility can make it easier for our target group to start with the program, but it may also make quitting the program easier. Our process evaluation will determine whether the flexibility of the program motivates or hinders (lasting) participation in the program.

CONCLUSION

This study protocol describes the Back2Balance program of which the impact on physical activity, healthy nutrition, social networks enhancement, and self-reported health will be evaluated. The program may have beneficial long-term effects: by improving health and increasing social networks we expect less health-related problems and less health care utility on the long term. Moreover, when shown (cost) effective the program can easily be implemented and continued by the municipality of Apeldoorn and used as input for other national or international initiatives aiming to increase health of low-income multi-problem households.

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