

**Date:** 19<sup>th</sup> of Mars, 2023

# **The ABEL Feasibility Study**

(Adherence, Better health, Exercise and Life satisfaction): A  
Randomized Controlled Trial

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## 1. The epidemic of obesity

Obesity, defined as “abnormal or excessive fat accumulation that presents a risk to health” (1) and a body mass index (BMI) of  $\geq 30$ , represents a major health challenge and economic burden for welfare systems worldwide (2,3,4). For the individuals affected, having obesity is associated with a broad range of adverse health consequences ranging from non-communicable diseases, such as diabetes type 2, metabolic syndrome (5), liver disease (6) and cardiovascular disease (7) to negative impacts on mental health (8), higher risk of urinary incontinence (9, 10) and can consequently lead to impaired quality of life (11). Today, approximately one out of five adults are categorized with obesity in Norway, and the trend in obesity rates is predicted to further increase, with the highest prevalence reported among women (3, 12, 13). More women than men are also at risk of developing severe forms ( $\geq 35$  BMI) of obesity (3,12).

A report from Menon Economics revealed that the three major economic impacts of obesity were: disease burden (costs related to the burden of obesity such as pain and shortened life span), productivity costs (loss of productivity in the labor market due to absence from work and other obesity-related health reasons), and medical costs (costs related to diagnosis and treatment of obesity-related conditions) (2). The total economic cost of obesity in Norway was estimated to be approximately 68 billion NOK yearly (2). Disease burden represented the highest cost (39 billion NOK), followed by productivity costs (17 billion) and medical costs (12 billion NOK) (2).

Living with obesity is reported to account for 80-85% of the risk of developing non-communicable diseases such as diabetes type 2 (14). Hence, women with obesity experiences a 28 times greater risk of developing diabetes type 2 than women of normal weight (15). Among women with BMI of  $\geq 35$ , this increases to a 92 times greater risk (15). Guidance on regular physical activity, exercise and healthy eating is traditionally the first measure taken for patient who undergo treatment for obesity (3). Physical activity is defined as “any bodily movement produced by skeletal muscles that requires energy expenditure above resting level” (16). Exercise is defined as “a regular and structured subset of physical activity performed deliberately with a specific purpose, for instance improving some aspects of health or physical fitness” (16). Increased physical fitness and improved health can reduce the risk of the adverse consequences of obesity, independently of weight loss (17,18, 19). Hence, physical activity and exercise can minimize the risk of premature mortality and further development of non-communicable diseases related to obesity (such as diabetes type 2) (20, 21, 22,). However, the health benefits of physical activity and exercise rapidly decrease if it is not performed regularly (23) Fewer women with obesity are reported to meet the Norwegian government's recommendation for physical activity (150 to 300 minutes of moderate-intensity or 75 to 150 minutes of vigorous-intensity per week), compared with normal weighted women (16 % versus 57%) (24, 25). Having multimorbidity because of obesity, is also associated with not following guidelines (26). Further research investigating methods on getting more women with obesity regularly active are therefore needed.

## 1.1 “Exercise as medicine”

Treatment for obesity in the primary healthcare service in Norway is largely coordinated by general practitioners (GP) (2). Today, GPs can prescribe “exercise as medicine” to patients with diabetes type 2, hypertension, obesity or cardiovascular disease (27). “Green prescriptions” (tailored advice and guidance on lifestyle factors related to development of disease, such as physical activity, exercise and healthy eating) was first founded in 2003 as an alternative to medical treatment for patients with diabetes type 2 and hypertension (28). Green prescriptions involve a specific target payment code for medical procedures “101”, meaning that GPs receive financial incentives to discuss physical activity and healthy eating with the patient (28).

However, 41% of GPs in 2006 reported that they had newer prescribed green prescriptions to their patients (29, 30). Attalin et al. (2012) reported that 63% of GPs listed patient’s non-adherence to the tailored advice they were given as main barrier for not implementing green prescriptions in their practice (31). Low adherence may be associated with that the current green prescription model is lacking sufficient follow-up of patients (29). To increase patient’s adherence, GPs are requesting a follow-up alternative that includes social support, nutritional guidance, and reduced costs for exercise participation (29). Low adherence can also be associated with that GPs are found to have less positive attitudes towards health promotion in primary health care (32). Attalin et al. (2012) reported that only 52% of GPs wished to acquire skills in consulting patients on physical activity and exercise (31). Thus, increase GPs knowledge on mental and physical health outcomes by utilizing exercise as medicine, may also rise the use of green prescriptions. According to the “ABC framework for prescribing exercise as medicine” developed by O’Regan et al. (2021) (33), it is highlighted that providing patients with in-person coaching is essential to maintain adherence. Lundqvist et al. (2019) (34) observed that patients who received structured coaching by health personnel for six months became more active, and coaching was also correlated with positive predictors for exercise and physical activity adherence (self-efficacy and stages of change) (34). This was also observed in patients with obesity, where offering in-person coaching and social support was the greatest promoters for exercise adherence (35). The “ABC framework” also states the importance of establishing collaborations with professions such as exercise professionals to be able to provide sufficient individualized follow-up and coaching of patients (21, 35). This was confirmed by Tulloch et al. (2005) (36), where the most effective intervention to improve exercise adherence among patients was a collaboration between GPs and exercise professionals. Therefore, in-person coaching by an exercise professional may have the means to get more patients with obesity regularly active, and can potentially be the follow-up alternative the current green prescription model is lacking (35,37).

Considering the expenses and practical considerations associated with in-person coaching, has former studies displayed the advantage of web-based behavioral support for patients with lifestyle diseases such as obesity (38). It is a timesaving, cost effective, and can potentially be an important contributor for a sustainable green prescription model. However, web-based behavioral support often proves to have poor completion rate, and need to be combined with

face-to-face guidance and feedback in order to increase adherence (39, 40). For instance, Elley et al. (2019) (41) observed that a follow-up model, consistent of a combination of in-person exercise coaching and telephone calls improved adherence to exercise and physical activity. However, when combining in-person coaching and web-based behavioral support, there is still limited knowledge on how frequent in-person coaching needs to occur, in order to increase adherence. For instance, Ries et al. (2003) (42) observed that providing patients with monthly in-person coaching, and weekly telephone calls on the non-supervised weeks, only produced modest improvements in adherence. More knowledge on frequency of follow-up is therefore essential for an approach towards an economical sustainable green prescription model. For example, mean costs per patients for different frequency of in-person coaching are: four sessions monthly: 2400 NOK/monthly per patient. two sessions monthly 1500 NOK/monthly per patient NOK or one session monthly. 1050 NOK/monthly per patient. In discrepancy, the potential expense of sessions with an exercise professional may be profitable in the long run, and the general mean cost per patient for in-person follow-up is lower compared with the current costs associated with obesity and non-communicable diseases (2).

## 2. Purpose

The ultimate ambition of this project is to identify an economical sustainable model to get women with obesity regularly active, with improved health and physical fitness, and thus lower risk of developing severe health challenges.

The current study will be the first step in the development of such a model, where we aim to conduct a pilot/feasibility study to prepare for a large-scale study by establishing estimates of effect sizes, and to investigate barriers for successful implementation.

The ABEL Feasibility Study will evaluate the effect of three follow-up models with different frequency of physical follow-up by an exercise professional, on exercise adherence and total physical activity level. A secondary objective of this project is to evaluate if these follow-up models can improve mental and physical health and physical fitness in women with obesity. Finally, we aim to identify potential barriers to successful implementation of a “green prescription” among participants, GPs and exercise professionals.

### 2.1 Research aims

1. In women with obesity ( $BMI \geq 30$ ), what is the effect of in-person exercise coaching (high vs. medium vs. low dosage) on exercise adherence and total physical activity level?
2. In women with obesity ( $BMI \geq 30$ ), what is the effect of in-person exercise coaching (high vs. medium vs. low dosage) on mental health variables (quality of life, self-efficacy and barriers and motivation to exercise)?

3. In women with obesity (BMI $\geq$ 30), what is the effect of in-person exercise coaching (high vs. medium vs. low dosage) on health (glycated hemoglobin, cholesterol, blood pressure, waist circumference, BMI and urinary incontinence) and physical fitness (aerobic endurance, muscular strength)?
4. Is adherence to exercise and succeeding health effects associated with the exercise professionals' level of education and knowledge base?
5. What are the participant's experiences, barriers and facilitators of participating in the ABEL-project?
6. What are the general practitioners' experiences, barriers and facilitators of using the "green prescription"?

## 3. Method

### 3.1 Women with obesity (n =200)

In the present feasibility study, women with obesity (BMI of  $\geq$ 30, n=200) will be recruited to a 20-week randomized control trial (RCT) with four arms (Table 1). The groups are provided the same frequency (each week) of follow-up by the exercise professional, with a different dose of in-person exercise coaching and web-based behavioral support. Enrollment will be limited to age between 18 to 65 years, no fitness club membership six months prior to recruitment, low-active (<150 minutes of moderate-intensity or 75 minutes of vigorous-intensity per week), Norwegian speaking, and in possession of a smartphone. Exclusion criteria's are: chronic disease or pathology (e.g severe hypertension 180/110 mm Hg), heart disease or lung disease hindering exercise, changing GP during the intervention, functional impairment due to injuries hindering physical activity and exercise, and traveling during the intervention period, or at the time baseline and follow-up measures will be conducted.

Participants will be recruited via social media platforms (Facebook and Instagram) from rural (Sandnessjøen, Narvik, Svolvær, Sørumsand, Sogndal and Førde) and urban locations (Oslo, Bergen, Stavanger, Tromsø, Bodø and Arendal) spread across Norway. An advertisement on Facebook and Instagram will be posted, including contact information to one of the project fellows. Interested participants can contact the research fellow, and is informed to contact their GP. Due to practical reasons associated with the geographical spread of the project, members from the project group at NSS are not able to perform health screening of all participants. Therefore, to ensure that none of the participants have any contraindications for participating in the project, all participants will undergo a general health screening at their GP.

Table 1. Intervention arms (High, medium and low dosage in-person exercise coaching and control).

<b>Intervention arms</b>	
<p><b><u>HIGH dosage in-person exercise coaching</u></b></p> <p>n= 50</p>	<p>One in-person exercise session with the exercise professional/weekly.</p> <p>A total of 20 hours of in-person coaching during the 20 weeks of intervention.</p>
<p><b><u>MEDIUM dosage in-person exercise coaching</u></b></p> <p>n= 50</p>	<p>Two in-person exercise session with the exercise professional/monthly, and 15 minutes web-based behavioral support on the non-supervised weeks.</p> <p>Total of 10 hours in-person coaching during the 20 weeks intervention.</p>
<p><b><u>LOW dosage in-person exercise coaching</u></b></p> <p>n =50</p>	<p>One in-person exercise session with the exercise professional/monthly, and 15 minutes web-based behavioral support on the non-supervised weeks.</p> <p>Total of five hours of in-person coaching during the 20 weeks intervention.</p>
<p><b><u>Control group</u></b></p> <p>n = 50</p>	<p>Will be asked to continuing with normal life, and will receive regular follow-up care from their GP. This group will be giving the “Norwegian Directorate of Health’s” recommendations for physical activity and nutrition (43) and will have access to the ABEL-app in order to register physical activity and exercise, but will not be provided any coaching during the 20 weeks.</p>

For group HIGH, MEDIUM and LOW dosage of in-person exercise coaching, the exercise professionals will prescribe exercise programs tailored to the individual needs, as well as give advice about healthy eating and a balanced meal plan, including ideas, recipes and shopping lists. All participants will also get access to a web-based behavioral support (ABEL technologies), where individual exercise programs will be available, as well as nutritional guidance, graphs for progression and motivational notifications for achievement of goal settings. Via the ABEL-app, participants will enter physical activity and exercise data (type of activity, duration, intensity, frequency etc.), including the sessions without the exercise professional. The parameters that are logged in via the ABEL-app include rate of perceived exertion (RPE) for all activity, duration, intensity and type of activity. Weight lifted will also be logged for resistance exercise.

### 3.1.1 Exercise professionals (n=25)

A total of 25 exercise professionals, working full time as a personal trainer will follow up the participants at one of the following fitness clubs: Feel24, PT-group, Nr1 Fitness, Trento or Spent. These fitness clubs are located in the same area the participant lives and receives regular follow-up care from their GP. To minimize error caused by limited knowledge of the ABEL-app, and to ensure that the exercise professionals know how to use this system for

coaching participants and data collection, the exercise professionals have finished a web-based onboarding program, consisting of six modules, of 45 to 60 minutes. In the five first modules, the exercise professionals were educated in the functionality of the ABEL-app. The sixth module was led by two members from the ABEL-project group, where the exercise professionals learned how to conduct testing of participants and instructed in standardized test protocols. In addition, instruction videos for all test protocols will be uploaded on the ABEL-app.

To be included in the research project as an exercise professional, the qualifications and requirements are:

- A minimum of three years' experience working part-time as a personal trainer, and delivered  $\geq 80$  training sessions/per month, in three of the last five months, with one of the following qualifications:
  - 1) Higher education: bachelor/master in sports science, or other relevant health education (physiotherapy, nursing, osteopath, chiropractor).
  - 2) Practical experience: A personal training education (one-year education/60 credits), well as 2000 hours of delivered exercise sessions with clients.
- Completed an exam, developed by researchers at NSSS and Kristiania University College, that covers knowledge in: central elements of exercise (anatomy, physiology, biomechanics, aerobic endurance, and muscular strength), physical activity and health, coaching and motivation, source criticism and methodology, and exercise among patients with obesity. The test scores will be used to evaluate associations between the exercise professionals' level of competence and participants adherence to exercise and/or improvement in health and physical fitness. The project will therefore also obtain informed consent from the exercise professionals.
- Signed "professional ethics guideline" document.
- Completion of "Norway's Anti-Doping Agency's" and "Norway's counseling About Eating Disorders eLearning module.

### 3.1.2 Random allocation

Each participant will be randomly assigned (1:1:1:1) to one intervention group, HIGH, MEDIUM, LOW or CONTROL following a simple computer-based randomization program. All participants included in the study will conduct the baseline assessments before the randomization procedure. The study design will not allow for further masking of study participants or the exercise professional (caregivers to the interventions). Those from the research group involved in inclusion of the participants or follow-up measurements will not have access to the group allocation list. Further, all measurements will be completed and plotted without the research group information of group allocation. The statistical analyses will be done in SPSS, following a predefined analysis plan and before unmasking the study arms.



### 3.2. General practitioners (n=8)

In addition to the RCT, the project will recruit GPs (n=8) from clinics at the rural and urban locations to participate in an in-depth interview with researchers from NSSS (see 3.3). GPs will be recruited to provide more in-depth understanding on reasons for what the current green prescription model is lacking.

### 3.3 Outcome measures

Data will be collected at baseline, continually during, and immediately following the intervention period.

#### **Monitoring adherence to subscribed exercise sessions:**

Measures of adherence will be collected through the ABEL-app. Sessions performed with the exercise professional will be logged through the ABEL-app of the exercise professional, while sessions performed independently will be logged through the ABEL-app of the participant. Adherence will be measured by attendance (percentage of exercise sessions completed out of exercise sessions offered), as well as intensity (physical exertion of sessions) and duration (duration of sessions) (44).

#### **Questionnaire** (*approximately 25 minutes to complete*):

- **Background information:** Covering age, smoking, level of education, household income. In addition to information about physical activity behavior (fulfillment of physical activity recommendations, as well as weekly frequency, duration and modes of physical activity).
- **Health-related quality of life:** Will be measured by a Norwegian version of The MOS 36-item short-form health survey (SF-36) (45).
- **Self-efficacy:** Will be measured by a Norwegian abbreviated validated version of the Self-Efficacy Survey developed by Sallis et al. (46).
- **Perceived social support from family and friends:** Will be measured by a Norwegian version of a previous validated survey (47).
- **Stages of change:** Will be measured with a previously conducted questionnaire on exercise professionals' effect on changing attitudes towards physical activity according to upward moving in the stages of change model (48). To achieve high cross-language validation when translating the English version into Norwegian language, we used a forward-backward translation technique, involving three members of the research group. A bilingual acquaintance of the research group with English as mother tongue will finally assured the quality by comparing the "new" English version" with the original version.
- **Barriers to exercise:** Questions will be based on identified barriers in a previous study among Norwegian adult population (n= 12 504) (49) and among fitness club members (50). Eighteen barriers will be included in the questionnaire.
- **Motivation for exercise and physical activity:** Will be measured by a Norwegian version of the validated survey BREQ-2 (51).

- **Urinary incontinence:** Will be measured using a Norwegian version of the Incontinence Questionnaire-Short Form (ICIQ-UI SF) (52). Awareness and knowledge about pelvic floor muscles exercises will be assessed by single questions: “Do you do pelvic floor muscle exercises?” If yes, how many times weekly?” “If yes, has your exercise professional provided you any coaching on pelvic floor muscle exercises?”

At follow-up, we will add questions regarding how satisfied participants are with the digital and physical follow-ups, as well as perceived social support from their exercise professional during the trial period.

### **Health factors:**

- **Blood pressure, waist circumference and BMI:** Measures of blood pressure, waist circumference and BMI (height and weight) will be conducted during health screening at the GP. These variables are strongly associated with development of non-communicable diseases and can therefore be a low-cost indicator of general health which is minimally intrusive for the participant (53). Data will be scanned and sent to NSSS via password protected zip-files after the posttest, and stored on a secure data area.
- **Glycated hemoglobin and cholesterol:** Testing self test kits (Tigeni, Norway) will be given to all participant at baseline and follow-up for collection of blood sample markers: glycated hemoglobin and cholesterol (LDL, triglycerides and HDL). All values will be collected through capillary blood drawn from finger pricks. The participants will conduct the finger pricks test at their respected fitness club. The samples will be collected via DHL and sent to Tigeni for further analyses. Data will be collected by the GP and sent to NSSS via password protected zip-files after the posttest and stored on a secure data area. These testing kits have been shown to be reliable and valid for testing for markers as described above (54), and are considered to be practicable for the participants (55). Furthermore, due to the spread among the participants geographically, there is a need for achievable methods for collecting these markers.

### **Physical fitness:**

The exercise professionals will be conducting physical tests of the participants at baseline and at the end of the 20-week follow-up, to evaluate the individual progress in strength and aerobic endurance. The tests will be performed in the same order (aerobic then strength) at baseline and follow-up, with a standardized rest interval of 10 minutes between aerobic and strength measures. The results from strength testing will be sent to NSSS via password protected zip-files and stored on a secure data area. The results from aerobic testing will be logged analog, and sent to NSSS via mail, and plotted manually on secure data area.

- **Aerobic endurance:** Will be assessed with a standardized incline treadmill-walking test. Changes in working heart rate, reported RPE, and changes in heart rate recovery

after the test will be used to assess relative changes in aerobic capacity (56). Each participant will use the same treadmill at baseline and follow-up in order to avoid any speed and incline variations between different treadmills. Optical heart rate sensors (Polar Verity Sense) placed on the upper arm will be used for optimal heart rate recordings. Speed will be set at a constant of 6 km/h throughout the test, while inclination starts at 0%, and increases by 2% every three minutes. Heart rate and RPE values within the last 30 seconds of each load will be noted and used for estimation of intensity at each inclination. The exercise test will be stopped when the participants reach a reported RPE value of 16 or more, and the participants are asked to stand still and up right for two minutes. Heart rate values at one and two minutes will be recorded and used as measurements for heart rate recovery.

- **Muscular strength:** Will be assessed by a 1-RM estimation test in: chest press, close grip lat pull down and leg press. All exercises will be performed on the weight machines available at the specific location, and may therefore be slightly different. However, each participant will be tested on the same machine at baseline and follow-up. Two to three days before the 1-RM estimation test (test day), participants will undergo a familiarization session using each of the exercise equipment, according to the recommendations by Balady et al. (2000) (57). A load the participant perceives as low intensity will be selected for practice of correct lifting and breathing techniques (57). Practice continues until the participant demonstrates proper technique using submaximal loads, in all exercises for 10 repetitions. Participants will be asked to complete 10 repetitions for warm-up, using the load performed at the familiarization session. Thereafter, the load will progressively be increase until the participant reaches nine or less repetitions. Resting periods between attempts will be two minutes with a maximum of six attempts, and three minutes between each specific exercise. Brzycki 1-RM prediction equation (58) will be used to estimate the 1-RM based on the resistance and repetitions performed. The equation is mathematically expressed as  $1RM = W / [102.78 - 2.78(R)] / 100$ , where W is the weight used and R is the maximal number of repetitions performed.

#### **In-depth interview:**

- **Women with obesity (n=15):** In parallel with the RCT, 15 participants from the intervention groups (HIGH n = 5, MEDIUM n = 5, LOW dosage n = 5) will be recruited to participate in a semi-structured in-depth interview (approximately 60 min). The interview will be led by researchers from the project group, audiotaped and transcribed verbatim. An interview guide with open-ended questions will be developed by the project group, and based on: 1) Basic Psychological Needs in Exercise Scale (BPNES) (59, 60), that assess the extent to which the psychological needs of the participants were fulfilled during the intervention. BPNES includes three subscales, with four statements per subscale, to assess autonomy, competence, and relatedness. 2) A former investigation in Norway, including 14 questions designed to address factors associated with exercise adherence and drop-out (61). With regards to

the purpose of this project, we will also add questions regarding how satisfied participants were with in-person and digital follow-up by their exercise professional.

- **General practitioners (n=8):** The GPs recruited in the project will participate in a semi-structured in-depth interview (approximately 45 min). The interview will be led by researchers from the project group, audiotaped and transcribed verbatim. Questions will be based on a previous qualitative study from 2006, conducted on GPs in Norway (29).

### 3.4 Data analysis

All statistical analysis will be performed using SPSS Statistical Software (IBM Corp. Released 2016. IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp). Difference in outcome measures between the groups will mainly be evaluated using analysis of variance (ANOVA), multivariate analysis of variance (MANOVA) and analysis of covariance (ANCOVA) The association between the exercise professional's level of education and knowledge base and participants adherence to exercise and/or improvement in health and physical fitness, will be assessed using linear regression, controlling for confounding variables. Data will be presented as frequency, percentage or mean with standard deviation (SD). Transcripts from the in-dept interviews, will be analyzed using thematic analysis.

### 3.4 Ethical considerations

The ABEL-project was reviewed by the Regional Committee for Medical and Health Research Ethics (REK) November 2022. REK concluded that, according to the “Act on medical and health research” (the Health Research Act 2008), the project did not require full review. The project was accepted at Norwegian Centre for Research Data (NSD) January 2023, and will be registered at ClinicalTrials.gov and NSSS Ethical committee. According to the Declaration of Helsinki, all participants will receive written information about the project's purpose and procedures and give consent to participate. Participation in this project will not involve any harmful or invasive investigations. It will be emphasized that participation is voluntary and that anyone who chooses to participate could withdraw partially or fully from the project at any time without further explanation. The participants will receive membership at a fitness club, regular follow-up sessions with an exercise professional (working as a personal trainer), and access to the ABEL-app. No other economic compensation will be given to the participants. Based on Norwegian regulations, all raw research data will be kept for at least five years after study completion. The IT department at NSSS provides storage services.

## 4. Implementations

### 4.1 Project group

The project group at NSSS has several publications in peer reviewed journals, and a strong portfolio within “physical activity as medicine”. The ABEL-project is a collaboration between NSSS and the Kristiania university, where the project group has extensive experience with health research in various fields: fitness club members, preventive health care, exercise and sport science, behavior change, mental health (self-efficacy, life satisfaction, and psychological effects of exercise), strength training, as well as randomized control trials. The project group will have monthly updates or meetings. A total of two professors, one associate professor, one researcher and one research assistant are involved in the ABEL-project.

### 4.2 Project management and organization

The ABEL-project is organized and planned by NSSS and Kristiana university college, and carried out at the five fitness club chains in Norway. The project emerged as an initiative from Abel Technologies who approached researchers at NSSS and Kristiana university college.

ABEL Technologies partly finances the project and contribute with assistance in recruiting exercise professionals and participants, as well as providing training in the use of the Abel digital platform. However, Abel Technologies have had no influence on the scientific decisions when designing the RCT. Nor will they take part in writing, analyzing or interpreting data. The recruitment of exercise professionals began fall 2022, and recruitment of participants is planned to begin in February 2023. Start-up of the intervention, questionnaire, test protocols (physical test) and blood tests, are planned to be conducted in February 2023 (Table 2). Data analysis and dissemination of results are planned to begin in August 2023. During data collection, we will recruit master students from NSSS and Kristiania university college, who will have access to some of the collected data to write their own master-thesis. The results of the ABEL-project are planned to be published as six scientific articles, covering each research questions, submitted to international peer reviewed scientific journals.

Table 2. The projects milestones.

TASK	Quarter/2022/2023			
	4/22	1/23	2/23	3/23
Development of intervention, questionnaire and test protocols				
Recruitment and start-up of the intervention				
Termination of intervention				
Analysis and dissemination				

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