NORWICH CTU

Statistical Analysis Plan (SAP) for

READY - feasibility

Title: A Randomised controlled trial of Energetic Activity for Depression in Young people (READY): A multi-site feasibility trial protocol

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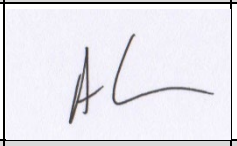
Allan Clark	Trial Statistician		06/06/2022
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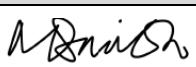
Megan Smith	Acting Trial Manager		12/07/2022
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1 CONTENTS

2 INTRODUCTION

2.1 TRIAL BACKGROUND:

Depression in adolescents

Existing research demonstrates that depression among adolescents is highly prevalent worldwide and that rates have increased significantly since the 1980s [1-3]. The risk of depression rises sharply as children transition into adolescence, with prevalence estimates of depression reported to be between 4-11% in mid-to-late adolescence and up to 20% by late adolescence [3-5], although prevalence estimates vary widely across studies and countries [4].

A significant noted trend is the rise in prevalence of depression among adolescent females compared to males, estimated at 2:1 [1-4, 6-10]. In childhood no differences are observed, but by 13-15 years, more girls are diagnosed as depressed compared to boys [11]. The reasons for this trend are not fully understood but may be related to hormonal changes during puberty, or the tendency for greater internalization of emotion in girls [4]. These findings are supported by a recent large-scale survey of 5,335 school-aged children in England (aged 11-15) which found poorer emotional health and wellbeing among adolescent girls compared to boys [12, 13].

Collishaw and colleagues [1] compared emotional problems in English 16-17 year olds between 1986 and 2006 and found twice as many young people reported frequent feelings of depression or anxiety in 2006 compared to 1986, especially girls. Also of relevance is that Lesbian, Gay, Bisexual and Transgender young people report experiencing depression and anxiety, suicidality and self-harm at considerably higher rates than heterosexual young people of a similar age, thought to be due to factors such as homophobic, biphobic and transphobic bullying at school and perceived stigma [14, 15]. Research in the United Kingdom (UK) and other high-income countries suggests that depression is more prevalent amongst people from Black and Asian Minority Ethnic (BAME) backgrounds [16, 17]. This likely reflects a complex interplay of factors such as social disadvantage, acculturative stress, and discrimination [17, 18].

Recent research suggests that adolescents who seek help do benefit from contact with mental health services. The ROOTS longitudinal cohort study conducted in the UK [7] found that contact with mental health services by 14 year olds with depression reduced the likelihood of depression by age 17 years. This is particularly important as it is known that many young people with depression do not access mental health services, estimated at 34-56% internationally [7] , or delay seeking help, increasing the duration or risk of recurrence episodes [7]. There are also concerns regarding the use of antidepressant drugs for adolescents younger than 18 years, with a recent systematic review and meta-analysis suggesting that antidepressant use among children and adolescents poses an increased risk for suicidal thoughts and aggressive behaviour [19]. There is also a lack of strong evidence regarding the effectiveness of psychological treatments, such as Cognitive Behavioural Therapy (CBT) and Interpersonal Psychotherapy (IPT) [4]. This suggests the need for alternative approaches such as promoting changes in behaviour and health behaviours such as exercise.

Exercise, high intensity training, and depression

There are several mechanisms that have been proposed to explain the many ways by which physical activity may be beneficial in the management of depression [20]. Some of these might be via social mechanisms; physical activity participation can provide a diversion from depressive thoughts, opportunities to learn new skills, and increased socialisation [21]. In addition, there may be physiological mechanisms; physical activity is associated with promoting the release of endorphins and other neurotransmitters which can improve mood [22]. Further, inflammation has been identified as a potential contributor to the development of depression [23], suggesting that anti-inflammatory strategies, such as regular physical exercise [24] may be effective at preventing and managing depressive symptoms. However, the optimal intensity of exercise required has not been established and this information is critical when determining prescription.

Moderate levels of exercise have been shown to increase myokines which could have a positive impact on inflammation [25] and hence depression. In recent years it has come to light that performing very short bursts of high intensity exercise (30 seconds) followed by 30 seconds rest repeated for four minutes has produced increased fat oxidation and increased maximal oxygen uptake [26]. Furthermore, research has suggested that high intensity interval training (HIIT) can promote anti-inflammatory effects during recovery [27], and therefore could be beneficial for diseases with an inflammatory response [28, 29]. There remains considerable uncertainty about the extent to which exercise intensity is related to benefit for depression.

Exercise for adolescents with depression

There is growing evidence that exercise may be an effective intervention to reduce depressive symptoms in adults [30-33]. A recent meta-analysis of exercise as a treatment for depression for adults, found a large significant effect on depression, with a larger effects for outpatients, in samples without other clinical co-morbidities and when exercise was supervised [32]. For adolescents with depression the evidence base is scarce and evidence quality is poor.

A Cochrane review in 2006 [34] and subsequent systematic reviews in 2013, 2016 and 2018 [35-37], respectively) examined the effects of exercise interventions in reducing depression and anxiety in children and adolescents. Larun et.al. [34], and Brown et.al. [35] found a small effect in favour of exercise. Carter and colleagues [36] found a moderate effect on depressive symptoms in clinical samples. Bailey et.al. [37] also reported that exercise was an acceptable and feasible intervention for this target group, with low dropout. However, the low quality of the studies reviewed, the small number of studies included, small sample sizes, and a diversity of participants, interventions and methods of measurement limit the ability to draw conclusions. A recent pragmatic small scale RCT [38] conducted in the UK reported no effect on depressive symptoms at post-intervention, but a significant effect at six months in favour of the intervention, suggesting a delayed response. The qualitative component of the study [39] reported that many of the young people found the exercise motivating and enjoyable and experienced low mood and disappointment at the end of the programme. The authors concluded that large, well reported and robust trials conducted with help-seeking young people in real-world treatment settings are required.

What is the problem and why now?

Adolescence is a significant risk period for the development of depression, associated with wide ranging long-term detrimental impacts on young people's wellbeing, mental health, social, and educational outcomes [2, 40]. Adolescents with depression are a group currently underrepresented in research, underserved by child and adolescent mental health services and at high risk of continued mental health problems into adulthood. There is an urgent need to offer feasible, acceptable and cost-effective treatment options for this neglected group of young people, given the limitations and potential risks of pharmacotherapy treatment and long waiting times for

psychological support. There is growing evidence that exercise is a helpful treatment for depression in young people [37, 39] but existing studies are generally small and poor quality and there remains a lack of strong evidence of cost-effectiveness. Our proposed research is clearly needed now, learning from previous research but moving forward with a definitive large-scale trial, with a clinical sample and conducted under 'real world' conditions.

Adding to the body of knowledge

Current NHS policy and practice regarding exercise for the treatment of clinical depression among adolescents is guidance-based rather than the provision of a structured and supervised exercise intervention. NICE clinical guidance [41] recommends that adolescents with depression should be offered advice on the benefits of regular exercise and encouraged to follow a structured and supervised exercise programme of up to three sessions a week, 45-60 minutes, for 10-12 weeks. However, this guidance is based on weak evidence (level IV) lacking details on intensity due to a lack of high-quality studies in this area. This study is to ascertain the feasibility of a large, adequately powered, high quality RCT with a large clinical sample of help-seeking adolescents with depression.

We expect to add valuable knowledge regarding the clinical and cost-effectiveness of an exercise intervention and its 'real world' application in the NHS and other services, along with a comparison between low intensity and high intensity exercise. We expect to provide essential evidence for the young people who might benefit, NHS policy makers, commissioners and clinicians, who are seeking evidence-based and cost-effective interventions for this specific group of young people, to offer as routine NHS care. This objective is aligned with current mental health policy to expand access to innovative and effective interventions and provide new workforce solutions [8, 10]. Our research will also add important knowledge regarding successful partnership working across the NHS and local community organisations, such as Active Partnerships, in areas with diverse populations and deprivation, to improve mental health support for children and young people [9, 42].

In summary, the existing evidence suggests that exercise is a promising and acceptable intervention for adolescents with depression. There is clear need for high quality trials in this area, with larger clinical samples, to effectively inform the implementation of exercise programmes to reduce depressive symptoms in adolescents, and to assess the influence of exercise intensity.

2.2 OBJECTIVES:

The aim of this feasibility study is to ascertain whether a full-scale definitive study is feasible. The objectives are to:

- 1. Finalise development of the intervention and control, including the Education Component (with Behaviour Change Techniques) and the intervention manual for: i. A high intensity exercise intervention, and
- ii. A low intensity exercise intervention with matched energy expenditure, and
- iii. An active control group of social (non-exercise) based activities
- 2. Finalise development of intervention training programmes for staff
- 3. Examine the feasibility of delivering the intervention across 3 sites (Hertfordshire, Norfolk and Bedfordshire): i. Explore adherence to the intervention protocol by exercise professionals, including contamination in delivery between exercise arms.
- ii. Examine the feasibility of delivering trial interventions in community settings by the exercise providers in different areas

- 4. Establish the potential adherence and engagement to the intervention by young people: i. Examine the acceptability of the exercise interventions
- ii. Adherence to the intervention, and maintenance of exercise
-
- 5. Establish potential reach and representativeness i. Examine demographic patterns (e.g. religion, ethnicity, gender, socio-economic status) in participants and non-participants to inform the recruitment strategy for the main trial
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- 6. Examine the feasibility of delivering a randomised trial at scale: i. Estimate referrals, recruitment and retention rates
- ii. Compare referral pathways
- iii. Estimate adherence rates to exercise
- iv. Determine the acceptability of the interventions
- v. Explore the feasibility of collecting outcome and resource use data
- vi. Evaluate the safety of the trial interventions
- vii. Confirm the number of required sites and sample size for the main RCT

The findings will be used to refine the intervention and study delivery for the full-scale trial.

3 STUDY METHODS

3.1 TRIAL DESIGN

READY feasibility is a feasibility study with clustering at the group-level. The groups will be formed of approximately 9 participants. The study has three arms:

1. *High intensity exercise arm*: High intensity exercises of alternating training sessions (e.g. basketball, football, boxing drills – see supplementary file $ for full breakdown) beginning with a 10-minute warm-up, culminating with a 5-minute whole body cool down. Young people will perform four repetitions of 45 seconds of maximal effort exercise (>90% predicted maximal heart rate) with 90 seconds rest in between each repetition (approximately nine minutes). This will increase by 2 minutes and 15 seconds every two weeks (e.g. one repetition of 45 seconds of exercise and 90 seconds rest) for the first six weeks and 4 minutes 30 seconds (e.g. two repetitions of 45 seconds of exercise and 90 seconds rest) in the last six weeks. The final two weeks will be 12 repetitions (27 minutes of exercise). Heart rate monitors will be used to tailor each person's maximum intensity, and judge exertion in each session.
2. *Low intensity exercise arm*: Low intensity exercise of alternating training sessions (e.g. walking football, walking netball). These activities elicit a heart rate between 40-50% maximal effort based on the activity compendium. The sessions will follow the same warm up and cool down as the high intensity, but the overall exercise session will be longer (to energy match to high intensity). The first two weeks will start at 15 minutes of exercise with a two-minute break in the middle. This will increase by three minutes every two weeks for the first six weeks, and six minutes every two weeks for the second six week. The last two weeks will therefore consist of 38 minutes of exercise.
3. *Social (control) arm*: Social activities will include board and computer-based games, and group discussions, with the exact activities agreed upon by the group. The purpose of these control activities is to provide a comparative length of time and social context, which does

not involve exercise, to rule out any potential social benefits for depression of the two exercise conditions. The Healthy Living session will be almost identical to avoid introducing variables other than supervised exercise sessions into the study design. Young people in all three arms will be encouraged to engage in physical activity between sessions, and after the intervention ends to maintain their exercise levels.

For full details see the protocol methods, intervention measures and intervention sections.

3.2 RANDOMISATION

Randomisation will be in the ratio 1:1:1 by blocked stratified randomisation. The stratification variable will be site. The block size will be three.

3.3 SAMPLE SIZE

Eighty-one eligible young people at three sites (27/site) from Hertfordshire, Luton, and Norfolk from Child and Adolescent Mental Health Services (CAMHS), and from primary care GP practices. This sample size was selected to enable more than 20 patients per arm and allows for each of the 3 interventions to be completed at each of the 3 study sites, giving 9 groups in total. Each group needs to be at least 9 patients to ensure that at any given session at least 6 patients are present (allowing for 33% no show/drop out). As this is a feasibility study it is not powered to detect a difference in clinical outcomes between the two interventions. Therefore, no power calculation has been performed. We have estimated that a total sample size of 81 patients will be sufficient to estimate the recruitment rates and completion rates.

This was reviewed due to COVID related issues and a new target of 27 participants in total was set.

3.4 FRAMEWORK

READY feasibility is a feasibility study and as such is not formally testing hypothesis.

3.5 STATISTICAL INTERIM ANALYSES AND STOPPING GUIDANCE

No interim analyses will be undertaken for this study and no formal stopping rules will be implemented.

3.6 TIMING OF FINAL ANALYSIS

The final analysis will take place once the SAP is formally signed off and the database is locked. All outcomes will be analysed collectively in the same report.

3.7 TIMING OF OUTCOME ASSESSMENTS.

The timing of outcome assessments is given in the outcome section 6.1

4 STATISTICAL PRINCIPLES

4.1 CONFIDENCE INTERVALS AND P-VALUES

Confidence intervals will be presented at both the 95% and 80% level and will be two-sided. The decision to report the 80% confidence level, in addition to the 95% interval, has been taken so that the intervals are not overly wide.

4.2 ADHERENCE AND PROTOCOL DEVIATIONS

Adherence will be measured as part of the feasibility outcome measures. It is measured in two ways. Firstly, as the percentage of sessions attended. Secondly, as the percentage of time the heart rate is at the correct level for the intervention group; this is not recorded in the control group.

All major protocol deviations will be listed in tabular format.

4.3 ANALYSIS POPULATIONS

The analysis will be based on the intention-to-treat population defined as:

Intention-to-treat: All randomised participants regardless of their eligibility or adherence, according to the treatment arm they were randomised to receive.

5 TRIAL POPULATION

5.1 SCREENING DATA

The number of participants screened at each site and the reason for not participating in the trial will tabulated overall and for each site separately.

5.2 RECRUITMENT

The CONSORT diagram comprising the number of people screened, eligible, consented, randomised, receiving allocated intervention, withdrawing or lost to follow-up will be presented. Additional descriptive statistics on recruitment routes will also be provided, to aid the understanding of participant flow.

5.3 WITHDRAWAL/FOLLOW-UP

The numbers, with reasons, of loss to follow-up (drop-outs or withdrawals) over the course of the trial will be summarised by treatment arm at each time point.

5.4 BASELINE PATIENT CHARACTERISTICS

Baseline data will be presented using summary statistics by allocated group, the mean and standard deviation shall be used for continuous variables and the number and percentage for categorical variables. If the continuous variables are heavily skewed then the median and interquartile range will be used. If necessary, levels categorical variables may be combined for analysis. The table template is given below.

Table 1: Template for baseline table

		Social (n=)		Low intensity (n=)		High intensity (n=)
Age (years), mean (SD)	**N**	**Mean (SD)**	**N**	**Mean (SD)**	**N**	**Mean (SD)**
Gender, n(%)						
Male						
Female						
Other						
CDI II						
PANAS - positive						
PANAS - negative						
COM – B						
Physical Opportunity						
Social Opportunity						
Motivation						
Automatic motivation						
Physical Capability						
Psychologically able						
YPAQ						
Sports (mins/week)						
Leisure (mins/week)						
School (mins/week)						
BSFC						

Table 2: Data completeness template table

	Social (n=)			Low intensity (n=)			High intensity (n=)		
	Number expected	Number returned (%)	Number complete (%)	Number expected	Number returned (%)	Number complete (%)	Number expected	Number returned (%)	Number complete (%)
CDI II									
PANAS - positive									
PANAS - negative									
COM – B									
Physical Opportunity									
Social Opportunity									
Motivation									

Automatic motivation									
Physical Capability									
Psychologically able									
YPAQ									
Sports (mins/week)									
Leisure (mins/week)									
School (mins/week)									
BSFC									
Accelerometer									
Sedentary time									
Light activity									
Moderate activity									
Vigorous activity									
Total activity									

6 ANALYSIS

6.1 OUTCOME DEFINITIONS

Feasibility outcomes:

The outcomes used to assess the feasibility of conducting a full-scale RCT are:

a) referral rate;
b) recruitment rate per month per site;
c) trial retention rate;
d) attendance at exercise session;
e) adherence to intensity during exercise session using heart rate monitor;;
f) completeness of outcome measures at each time point.

Outcome Measures:

Child Depression Inventory 2nd edition (CDI-2). Is a self-complete questionnaire to measure depressive symptoms in youth aged 7-17 years. It consists of 28 questions and the total score ranges from 0 to 56, with higher values indicating more depression. The scoring system is given in the appendix.

Psychological measures:

- Positive and Negative Affect Schedule (PANAS), is a self-reported questionnaire with 20 question which results in two 10-item sub-scales for positive and negative effects.
- New General Self-Efficacy scale, an eight-item measure to assess how much young people believe they can achieve their goals to engage in exercise. Higher values indicate more self-efficacy.
- Multidimensional scale of perceived Social Support (MSPSS), a twelve-item measure designed to measure perceptions of support from family, friends and a significant other. Each
- A six-item COM-B measure asking participants how much they agree that they have the Capability (Physical and Psychological), Opportunity (Social and Physical), and Motivation (Reflective and Automatic) to be regularly active.

Carer Measures:

- Burden Scale for Family Caregivers – short form (BSFC-s. Ten-item scale to measure perceived burden on families.

Physical activity:

- Peak and average heart rate during the intervention sessions.
- Physical activity beyond the intervention sessions (accelerometer) and the Youth Physical Activity Questionnaire (Y-PAQ, [65])

Table 3: Schedule of outcome measurements

	Outcome measures +/- 7 days from randomisation			
Measurement	**Baseline**	**During intervention**	**Week 14**	**Week 26**
CDI 2	**X**		**X**	**X**
PANAS	**X**		**X**	**X**
New General Self-Efficacy Scale	**X**		**X**	**X**
MSPSS	**X**		**X**	**X**
COM-B	**X**		**X**	**X**
Burden Scale for Family Caregivers	**X**		**X**	**X**

Physical activity	**X**	**X**		
EQ-5D-5L	**X**		**X**	**X**
CHU-9D	**X**		**X**	**X**

6.2 ANALYSIS METHODS

Feasibility outcomes:

The recruitment rate per month will be tabulated and the rate per month estimated, confidence intervals will be estimated by assuming that the rate is distributed according to a Poisson distribution.

Retention rate will be estimated, as the percentage of individuals who withdraw from follow-up from each arm. It will also be displayed graphically using an inverse Kaplan-Meier plot.

Attendance will be reported, as the number of sessions attended out of the number of sessions invited to attend. The attendance will be estimated overall and for each week of planned activity.

Adherence will also be estimated as the number of individuals who maintain the heart for the duration of the session.

The completeness and attendance for assessments will be estimated for each assessment and each outcome separately.

No formal hypothesis testing will be undertaken for any of the feasibility outcomes and all analyses will be based on the intention-to-treat population.

The template for reporting these outcome is given in Table 4.

Table 4: Template for feasibility outcomes

Outcome	Social (n=)	Low intensity (n=)	High intensity (n=)	Overall (n=)
Recruitment rate				
Trial retention rate				
Adherence - attendance				
Overall				
Week 1				
Week 2				
...				
Week 12				
Adherence - heart rate				
Overall				
Week 1				
Week 2				
...				
Week 12				

Efficacy outcomes:

Descriptive statistics will be reported by randomised groups. Percentages will be of non-missing values. The number of non-missing values will be given if the data are not complete.

All outcome measures are continuous and will be analysed in a similar fashion. The aim of the analysis is to estimate the parameters required for the sample size calculation of the main trial, namely the standard deviation. The descriptive statistics of each outcome will be given per treatment arm.

The template for reporting the efficacy outcomes is given in Table 5 and will be reported separately at 14 and 26 weeks.

Table 5: Template for efficacy outcomes (descriptive statistics)

Outcome	Social (n=)	Low intensity (n=)	High intensity (n=)
CDI II			
PANAS - positive			
PANAS - negative			
COM – B			
Physical Opportunity			
Social Opportunity			
Motivation			
Automatic motivation			
Physical Capability			
Psychologically able			
YPAQ			
Sports (mins/week)			
Leisure (mins/week)			
School (mins/week)			
BSFC			
Accelerometer			
Sedentary time			
Light activity			
Moderate activity			
Vigorous activity			
Total activity			
EQ-5D-5L			
CHU-9D			

Sample size for main trial:

The sample size for the main trial will be calculated using the parameters estimated in this trial as well as external evidence. The minimally important difference in CDI II will be based on published literature, but the standard deviation and drop-out rates will be based on estimated values and the upper limit of an 80% confidence interval.

6.3 Missing data

The rate of missing data will be estimated for each outcome measure. As a feasibility no imputation of missing data will be undertaken.

6.4 Additional Analyses

No additional analyses are planned at this time.

6.5 Harms

The number of adverse events will be tabulated per randomisation arm and listed

6.6 Statistical software

The analysis will be undertaken by Allan Clark and will use Stata version 16, however, other packages such as R or SAS may be used if necessary.

7 Scoring systems for questionnaires

7.1 CDI-II

The sum of all questions from each question rated from 0 to 2.

7.2 PANAS

PANAS Questionnaire

This scale consists of a number of words that describe different feelings and emotions. Read each item and then list the number from the scale below next to each word. **Indicate to what extent you feel this way right now, that is, at the present moment *OR* indicate the extent you have felt this way over the past week (circle the instructions you followed when taking this measure)**

1	2	3	4	5
Very Slightly or Not at All	A Little	Moderately	Quite a Bit	Extremely

_____ 1. Interested	_____ 11. Irritable
_____ 2. Distressed	_____ 12. Alert
_____ 3. Excited	_____ 13. Ashamed
_____ 4. Upset	_____ 14. Inspired
_____ 5. Strong	_____ 15. Nervous
_____ 6. Guilty	_____ 16. Determined
_____ 7. Scared	_____ 17. Attentive
_____ 8. Hostile	_____ 18. Jittery
_____ 9. Enthusiastic	_____ 19. Active
_____ 10. Proud	_____ 20. Afraid

Scoring Instructions:

Positive Affect Score: Add the scores on items 1, 3, 5, 9, 10, 12, 14, 16, 17, and 19. Scores can range from 10 – 50, with higher scores representing higher levels of positive affect. Mean Scores: Momentary = 29.7 (*SD* = 7.9); Weekly = 33.3 (*SD* = *7.2)*

Negative Affect Score: Add the scores on items 2, 4, 6, 7, 8, 11, 13, 15, 18, and 20. Scores can range from 10 – 50, with lower scores representing lower levels of negative affect. Mean Score: Momentary = 14.8 (*SD* = 5.4); Weekly = 17.4 (*SD* = 6.2)

7.3 NGSE

This self-reported questionnaire asks respondents eight questions and the response is on five-point rating scale (1 = strongly agree, 3 = neither agree or disagree; 5 = strongly disagree). The score is the average response over all 8 questions. The questions are

Number	Question
1	I will be able to achieve most of the goals that I have set for myself.
2	When facing difficult tasks, I am certain that I will accomplish them.
3	In general, I think that I can obtain outcomes that are important to me.
4	I believe I can succeed at most any endeavour to which I set my mind.
5	I will be able to successfully overcome many challenges.
6	I am confident that I can perform effectively on many different tasks.
7	Compared to other people, I can do most tasks very well.
8	Even when things are tough, I can perform quite well.

7.4 MULTIDIMENSIONAL SCALE OF PERCEIVED SOCIAL SUPPORT

This is a self-report 12 item questionnaire. Each question has a response on the seven-point rating scale (1 = Very strongly disagree, 2= strongly disagree, 3 = mildly disagree, 4 = neutral, 5 = mildly agree, 6 = strongly agree, 7 = very strongly agree). It has a total score, which is the average response over the 12 items. The other scores are:

- Significant Other Subscale: Sum across items 1, 2, 5, & 10, then divide by 4.
- Family Subscale: Sum across items 3, 4, 8, & 11, then divide by 4.
- Friends Subscale: Sum across items 6, 7, 9, & 12, then divide by 4.

7.5 COM-B

Is a 6-item questionnaire asking about opportunity, motivation and physical ability to exercise. Each item is reported separately.

7.6 Y-PAQ

The YPAQ contains 47 different activities and requests participants to report the frequency and duration of each activity for both weekdays and weekend days over the past 7 days. The YPAQ is broken into contextual settings/domains: sporting, leisure, school and free-time activities.

7.7 Burden Scale for Family Caregivers

The short version of the Burden Scale for Family Caregivers (BSFC-s) is a 10-item instrument for measuring subjective burden in informal CGs. Each item is a statement that is rated on a 4-point scale with the values “strongly disagree” (0), “disagree” (1), “agree” (2), and “strongly agree” (3). The score is the sum of the response to each of the 10 items.

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