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Healthy Teens @ School: Evaluating and disseminating transdiagnostic preventive interventions for eating disorders and obesity for adolescents in school settings

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ABSTRACT

Background: The worldwide prevalence of overweight and obesity is at alarming levels. Nearly one in three children in Europe is overweight or obese. Disordered eating and body image concerns are equally widespread and increase risk for more chronic and severe weight-related problems. Research has shown that online interventions that address both healthy weight regulation and body image can reduce risk for eating disorders and obesity simultaneously and are feasible to implement in school settings. To date, evaluation and dissemination of such programs in Europe is scant.

Methods: The *Healthy Teens @ School* study is a multi-country cluster-randomized controlled trial (RCT) comparing the effectiveness of an unguided, online, multi-level intervention for promoting a healthy lifestyle and reducing problematic eating behavior, eating disorder and obesity risk among students aged 14 to 19 years with control condition. As part of the Horizon 2020 funded project ICare (GA No. 634757) the trial is conducted in Austria and Spain. Cluster randomization by school is used. The intervention is an adapted version of an evidence-based program developed in the USA (StayingFit). Participants of the intervention group are assigned to one of two possible program tracks based on the results of the initial online-assessment: Overweight adolescents are assigned to the "Weight Management" track emphasizing balanced eating and exercise for weight maintenance, and all other individuals are assigned to the "Healthy Habits" track which aims at promoting healthy habits related to e.g., nutrition, physical activity, sleep. The participants of both tracks work on ten modules (one 20–30 min module per week) during school hours and/or at home. Assessments are conducted at pre- and post-intervention, and at 6- and 12-months after baseline assessment. The primary outcome is intuitive eating, secondary outcomes are eating disorder symptomatology, body image concerns, body mass index, food intake, physical activity, self-esteem, stress coping, depression, and anxiety. Following the initial assessment, individuals in the control group do not have access to the prevention program but continue as normal and are only prompted to the assessments at all time points. At the end of the 12-month study they will get access to the program.

Discussion: The results from this study will add to the understanding of how to address eating and weight related problems in adolescents and will shed light on the feasibility of implementing online prevention programs in

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school routine in Austria and Spain. As part of the larger ICare project this RCT will determine how an adapted version of StayingFit is disseminated within Europe.

1. Introduction

The worldwide prevalence of overweight and obesity is at alarming levels (Ahluwalia et al., 2015; Odgen et al., 2015). Disordered eating and body image concerns are equally widespread and increase risk for more chronic and severe weight-related problems. Eating disorders (ED), symptoms of disordered eating and body dissatisfaction disproportionately affect young girls and women, yet health problems related to problematic eating and exercise habits impair all sexes and ages (Aschenbrenner et al., 2004; Delinsky and Wilson, 2008; Hay et al., 2008; Leon et al., 1997; Shisslak et al., 1995; Zeiler et al., 2016).

Binge eating, a common symptom of disordered eating, is also common in overweight and obese individuals (French et al., 1999; Zeiler et al., 2016), and is closely associated with depression, impaired work productivity, absenteeism, impaired non-work activity, poorer quality of life and social functioning, even more than obesity itself (Perez and Warren, 2012; Striegel et al., 2012). Frequent dieting, restrictive eating, and over-evaluation of weight and shape are the most potent and best replicated risk factors for full- and sub-threshold EDs (Jacobi et al., 2017). Preventive approaches targeting these risk factors and early ED symptoms are effective in both reducing ED-related attitudes and symptoms (Stice and Shaw, 2004; Stice et al., 2007) and the onset of ED syndromes (Taylor et al., 2006, 2016).

Unhealthy dieting is a risk factor for binge eating and is associated with the development of overweight and obesity (Cuypers et al., 2012). Thus, healthy weight regulation and eating behaviors are essential for preventing and treating EDs, ED symptoms and preventing disorders and sequelae related to overweight and obesity. Given the multiple interrelations between symptoms and syndromes of disordered eating and obesity, a comprehensive approach targeting all eating related problem behaviors is critical.

Structured prevention programs for both EDs and obesity have shown to be effective when administered in high-risk samples, while only yielding small effects in universal prevention directed at the general population (Jacobi et al., 2012; Stice et al., 2007; Taylor et al., 2006). Interventions directed at adult obesity are plentiful, yet research on online interventions for childhood obesity is limited. To produce persistent behavior changes comprehensive, targeted (selective and indicated) preventive interventions for specific high-risk groups of different ages are critically needed.

1.1. The need for online interventions for adolescents

In the adolescent age range, internet use is especially widespread with > 95% of European adolescents and young adults between 16 and 24 using the internet on a regular basis (European Commission, 2016). The Internet is a key source of health information for adolescents (e.g., Wartella et al., 2016) and technologies like mobile phone applications and Internet-based applications play an important role in the delivery of mental health services for adolescents (Boydell et al., 2014). To date, Internet- and mobile-delivered applications for children and adolescents comprise screening, pure psycho-educational interventions, (universal to indicated) prevention, assessment, diagnosis, counseling, (guided or non-guided) self-help intervention, treatment and relapse prevention (Boydell et al., 2014; Eng, 2001; Free et al., 2010; Muñoz, 2010; Riper et al., 2010). There is some evidence that skills- and module-based mental health promotion interventions have positive effects on adolescents' mental health and that computerized CBT can reduce anxiety and depression symptoms in adolescents. However, since the quality of evidence varies across studies, more rigorous research is warranted (Clarke et al., 2015).

It is commonly assumed that especially young people can benefit from interventions delivered online (Hollis et al., 2017). Greater anonymity may encourage adolescents to reveal more sensitive health information (Bradley et al., 2012). High accessibility and flexibility are perceived as further advantages of online programs (Pretorius et al., 2010) as well as high user acceptability (Das et al., 2016). Fleming et al. (2016) emphasize the great potential of online mental health programs to increase help-seeking and reach of adolescents. This is especially important from a public health perspective as more adolescents might be able to benefit from online prevention than from face-to-face interventions. Finally, depending on the amount and efficiency of guidance provided by the intervention, online programs for reducing progression of eating disorder symptoms in young people may be more cost-effective compared to face-to-face interventions (Kass et al., 2017).

1.2. Effects of online interventions for eating disorders and obesity

1.2.1. Eating disorders and symptoms of disordered eating

A suite of online ED prevention programs utilized in both universal and selective/targeted prevention approaches was associated with moderate improvements in ED-related attitudes, especially reductions of negative body image and the desire to be thin (Beintner et al., 2012; Jacobi et al., 2007, 2012; Taylor et al., 2006, 2016). Self-help interventions have been shown to contribute to bridging the treatment gap for bulimia nervosa and binge eating disorder, with 9–64% of participants achieving abstinence (Beintner et al., 2014).

1.2.2. Obesity

Behavior modification, dietary intervention, and physical activity are key elements in obesity treatment (Levy et al., 2007), yet, intervention availability, cost, adherence and long-term efficacy remain challenges. It is needed to develop effective weight loss programs that are time and cost-saving. The Internet offers an innovative delivery tool for obesity interventions, with the potential to offer long-term interventions at low cost (Manzoni et al., 2011). While interventions directed at adult obesity are increasingly investigated (e.g., Longin et al., 2012), research on online treatment for childhood obesity is scarce. Evidence for the efficacy of preventive interventions for obesity in children is insufficient yet, mostly based on uncontrolled studies. However, online interventions might have positive outcomes, including increased self-efficacy, reduction in weight and shape concerns, increased physical activity, decreased dietary fat intake, reduction in objective and subjective binge episodes, and healthier food choices and weight reduction (Kornman et al., 2010; Nguyen et al., 2011).

2. Materials and methods

2.1. Objectives and hypotheses

To strengthen the knowledge base, the *Healthy Teens @ School* study aims to evaluate the effectiveness of a transdiagnostic preventive intervention program for eating disorders and obesity (original US name: “StayingFit”; Jones et al., 2014; Taylor et al., 2012) for school-aged adolescents (14–19 years) in school settings in Europe. Specific hypotheses are: *Healthy Teens @ School* reduces problematic eating behavior, eating disorder risk, obesity risk and body image concerns and increases fruit and vegetable consumption. The program may also impact self-esteem, as well as symptoms of depression and anxiety.

Healthy Teens @ School is evaluated in Austria and Spain in a cluster-

randomized controlled trial (RCT). The results will be used to determine whether *Healthy Teens @ School* is appropriate for widespread implementation and dissemination as part of the larger ICare initiative.

2.2. Participants and recruitment

Participants are male and female adolescents aged 14–19 years who are normal weight or overweight from Austria and Spain.

2.2.1. Inclusion criteria

- Adolescents aged 14 to 19 years old enrolled at participating schools
- Access to and ability to use a computer with Internet
- Adolescents' as well as parental informed consents are available

2.2.2. Exclusion criteria

- Adolescents with a currently diagnosed mental disorder and/or currently in treatment due to a mental disorder
- Adolescents below a healthy body weight, as defined by BMI < 18,5 (adolescents aged 18+) or Ideal Body Weight (IBW) below 75% of that expected or with pronounced eating disorder symptoms

2.2.3. Recruitment in Austria

Principals from different types of schools including secondary academic schools and vocational schools are contacted via e-mail or telephone and invited to participate with the consent of regional supervisory school authorities. Schools who participated in a former epidemiological project on adolescents' mental health (Wagner et al., 2017) will be invited first but also other schools who express an interest in this project will be able to participate. Written information material is provided to students, parents and teachers and information events are held in schools who are interested in participating.

Since most participants in this trial are under the age of 18, written informed consent is obtained from one legal representative (in most cases mother or father). The participation in this study is only possible if the students return an informed consent signed by a legal representative as well as the assent signed by the adolescents himself/herself. Only those adolescents who return both (consent & assent) get access to the platform. In order to safeguard the confidentiality of the participants' personal information informed consent forms that include the full name of the participants are stored (only offline) in a locked room at the Medical University of Vienna. Only authorized personal has access to personal information.

2.2.4. Recruitment in Spain

Principals and teachers from different schools are contacted and invited to participate via e-mail with the consent of the ministry of education in Valencia Community. A meeting is held in schools who are interested to participate, where information and material are given to teachers and staff. Once the schools agree to participate, written

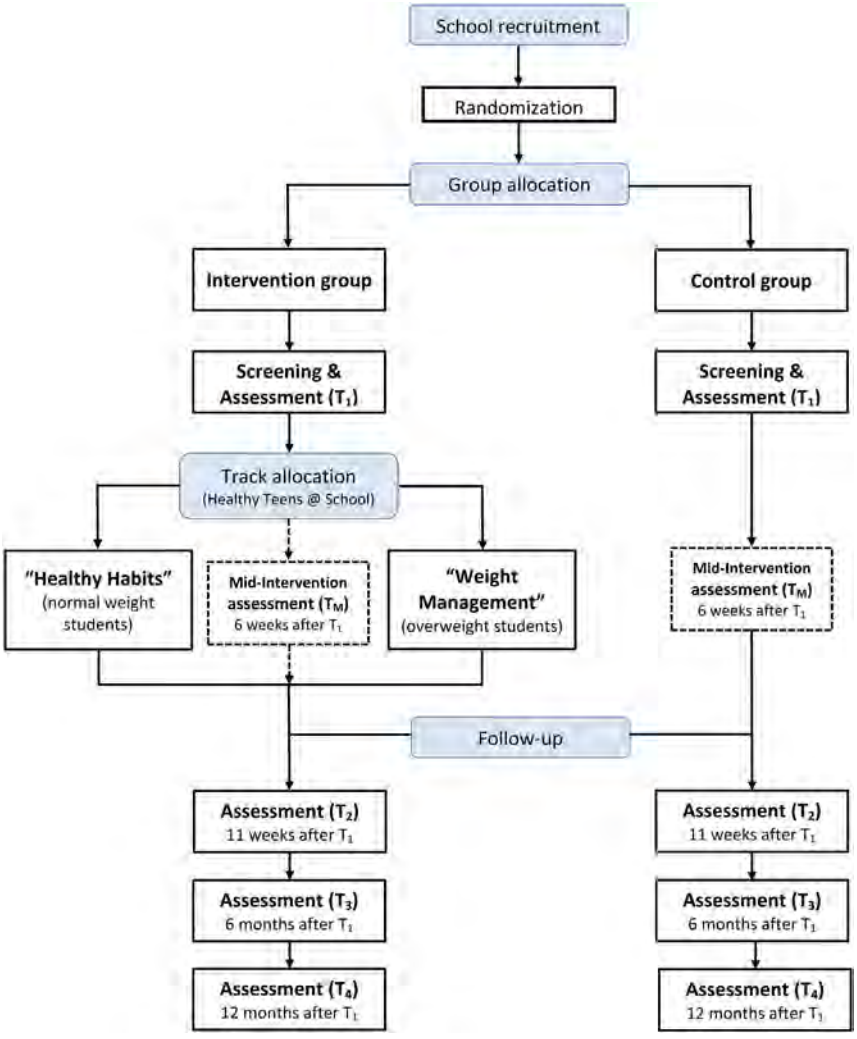

Fig. 1. Study design.

material with information about the study is disseminated to students and parents.

The participation in this study is only possible if the students return an informed consent signed by their parents or a legal representative. In Spain, the signatures of both parents are needed to obtain the permission. Furthermore, the adolescents' assent is obtained. Only those adolescents who return both (consent & assent) get access to the platform. In order to safeguard the confidentiality of the participants' personal information, informed consent forms that include the full name of the participants are stored (only offline) in a room locked with an electronic key at the University of Castellón. Only authorized personal has access to personal information, and a track of each access is stored.

2.3. Study design

This study is a multi-country cluster-randomized controlled trial (RCT) comparing the effectiveness of an unguided, Internet-based and mobile-supported, multi-level intervention for reducing problematic eating behavior, eating disorder and obesity risk and promoting a healthy lifestyle among adolescent students (*Healthy Teens @ School*, original US name: StayingFit; Jones et al., 2014; Taylor et al., 2012) with control condition. Cluster randomization by school is used. Schools that agree to participate in this study are randomly assigned to one of two groups, intervention or control group (randomization ratio 1:1, cluster randomization, see Fig. 1). Randomization is done by an independent researcher at the Institute of Biostatistics and Clinical Research (Münster, Germany). Students attending schools in the intervention group take part in the Internet-based prevention program *Healthy Teens @ School*. All participants complete an online questionnaire, which includes questions about weight and height, eating and physical activity habits, attitudes towards weight and shape, feelings, self-esteem and stress coping. Based on the results of the initial online-questionnaire, participants in the intervention group are allocated to one of two tracks to fit their specific needs. Overweight students as defined above the 85th sex and age specific BMI percentile take part in a program geared towards weight management (Weight Management track). All other students in the intervention group take part in a program about healthy habits (Healthy Habits track). Both tracks consist of ten modules where the participants learn how to build balanced eating and exercise habits, to improve their body image and to learn how to deal with difficult emotions and stress. The participants work on these modules (one 20–30 min module per week) during school hours and/or at home. Assessment is conducted at pre- and post-intervention (T_1 & T_2), and at 6- and 12-months (T_3 & T_4) after the T_1 (online-assessments). Additionally, a short assessment six weeks after T_1 is conducted to assess potential mediators of intervention outcomes (T_M). Following completion of the initial questionnaires, participants in the control group are not given access to the prevention program but prompted only to the assessments. By the end of the 12-months study (after assessment T_4) participants of the control condition receive access to the prevention program. The RCT is conducted in accordance with the CONSORT 2010 Statement (Eysenbach and CONSORT-EHEALTH Group, 2011; Moher et al., 2010; Moher, Schulz, Altman, and CONSORT Group, 2001).

Those adolescents who are identified with pronounced eating disorder symptoms (scoring in the clinically relevant range of the Eating Disorder Examination Questionnaire) and who therefore fulfill exclusion criteria get automatically feedback and the advice to consult a doctor or psychologist for further evaluation. They receive contact information for local specialized clinical services and have the possibility to directly contact clinical psychologists of the research team via the platform, e-mail or telephone to discuss the results.

To avoid stigmatization of adolescents who fulfill exclusion criteria, they also receive the “Healthy Habits” track, as this is a universal program which was useful for students without and with ED risk in previous studies (Jones et al., 2014). However, those adolescents who fulfilled the exclusion criteria will not be included in the statistical analyses.

Overweight and obesity are associated with high levels of stigmatization, particularly in adolescents. Thus, participants should be unaware of the two program tracks (“Healthy Habits” and “Weight Management”). The participants are told that they get a program that fits their needs based on their assessment results. There are reasons to fear that a full disclosure of the process of program allocation could lead to higher drop-out rates selectively of those adolescents who would probably benefit most from the programs.

The study protocol was approved by the Ethics Commission of the Medical University of Vienna (Austria, Record Number: 2209/2015) and the Ethics Commission of the University of Valencia (Spain, Record Number: H1453976699999). Furthermore, the conduction of the trial was approved by the local school authorities. The trial was registered at the ISRCTN clinical trial registry (record number: ISRCTN51957280).

2.4. Intervention

2.4.1. Minddistrict platform

All assessments and the prevention program itself are provided via the Minddistrict platform. All participants have a unique access to the platform. They have to login with a valid e-mail address and a self-chosen password (at least 12 characters).

A screenshot of the landing page of the platform is provided in the appendix (Fig. A.1). All unfinished tasks (e.g. assessments, new unlocked modules of the prevention program) can be accessed through “Tasks” (“Aufgaben”). Participants also get e-mail reminders, if new tasks (e.g. Follow-up assessments) are available for them. Although the software allows conversations between participants, this possibility is disabled in this trial. Under “contacts” (“Theraupeuten”) the participants can see the members of the local research team and can contact them if they want to (although a regular contact is not planned in this trial, as the program is totally unguided). Participants can contact the research team anonymously if they want to discuss any problems. Furthermore, a “diary function” (“Tagebuch”) is implemented in the platform. By the use of this function daily logs (e.g. food consumption, daily physical activities) can be recorded. This function should be used by the participants to monitor their own food consumption and physical activities as well as their stress levels on a daily basis.

The Minddistrict platform can be accessed by several electronic devices (computer, tablets, smartphones/iPhones). Additionally, a Minddistrict App exists, which the participants can use to complete the diaries.

2.4.2. Healthy Teens @ School prevention program

The StayingFit program originally developed at Stanford University (USA) was adapted for the European (Austrian and Spanish) context. After the baseline assessment, all participants of the intervention group are automatically assigned to one of two program tracks. Overweight adolescents (based on sex and age specific BMI percentiles) are assigned to the “Weight Management” track, all the other participants are assigned to the “Healthy Habits” track.

StayingFit-Healthy Habits was originally adapted from StudentBodies (Taylor et al., 2006), a CBT based program to promote healthy eating and exercise behaviors in teenagers. For US adolescents, the program was effective in reducing disordered eating behaviors, increasing fruit and vegetable consumption and physical activity, and for a subset of students with elevated weight and shape concerns, improving body image (Jones et al., 2014; Taylor et al., 2012). For the current trial, the program was translated into German and Spanish and adapted for normal weight adolescents with and without elevated weight and shape concerns.

StayingFit-Weight Management represents a parallel track of StayingFit Healthy Habits modified for overweight adolescents. It has been demonstrated to support weight loss, reduce binge eating, and

improve weight and shape concerns in at-risk for overweight and overweight adolescents in the US (Jones et al., 2014). For the current trial, the program was translated into German and Spanish and adapted for overweight adolescents focusing on balanced eating and preventing additional weight gain in the future.

The Healthy Habits track describes the goal of the program as developing healthy habits related to nutrition, physical activity and other habits such as sleep, coping with stress and difficult emotions. The Weight Management track emphasizes eating and exercise for weight maintenance. Track differences are primarily in the language used to describe the content and exercises, rather than the content itself. However, some content is extended in the Weight Management track (e.g. sections on red vs. green foods, emotional eating, relation between exercise and weight management, eating in "risky" situations) while some content is more emphasized in the Healthy Habits track (e.g. stress coping, assertiveness).

Adaptation of the Staying Fit Programs: Prior to the start of the study, the original US StayingFit programs were translated into German and Spanish and adapted for Austrian and Spanish populations. The program content was adapted based on the Austrian and Spanish recommendations on dietary intake and physical activities as well as on national conventions for ED prevention (e.g. focus on balanced nutrition and "nothing-is-forbidden"-approach rather than focus on calories and weight monitoring). Furthermore, due to results obtained in the course of a stakeholder survey, additional contents on dealing with stress and negative emotions were added since these topics were mentioned as the most important challenges in students' lives. Contents of an Internet-based personality focused prevention program for common mental disorders in young adults called "Personality and Living of University Students" (PLUS, Musiat et al., 2014) were adapted for adolescents and incorporated into the *Healthy Teens @ School* program. The stakeholder survey that is conducted as part of the ICare initiative aims at obtaining valuable information on the needs and attitudes towards Internet-based mental health prevention programs as well as relevant factors for their implementation and sustainability. Different types of stakeholders including stakeholders on the governing level (e.g. ministry of education), delivery staff (e.g. teachers, school psychologists, school physicians) and representatives of the target group (pupils) were included. Finally, the usability of the program components and platform function were tested in a usability study with Austrian adolescents and the program was adapted accordingly. Results of the stakeholder survey and the usability tests will be published in separate papers. The adaptation and translation process is depicted in Fig. 2.

Both adapted program tracks consist of 10 modules, which should be completed on a weekly basis. Each session includes approx. 10–15 pages of online content, targeted to a 9th grade reading level, designed to take approximately 20–30 min to complete. The session themes and further intervention components of the *Healthy Teens @ School* program are depicted in Table 1.

2.4.3. Implementation

Prior to implementation, the actual procedure of how the program will be used during school hours was developed with school teachers based on a participatory approach. Students have the opportunity to access their programs anytime outside of school hours during the active intervention phase. At least half of the program modules should be completed during school hours. The other half can be completed at home if the participating schools are not able to provide time for completing all modules during school hours.

At the end of each session, students are asked to answer questions about their learnings each week. Questions assess knowledge, attitudes, behaviors, and self-efficacy related to specific skills taught in the session. To measure student engagement and enjoyment of the material, students rate the level at which the content was helpful and interesting.

An additional (optional) mobile smartphone app with specific components, such as diaries (food intake physical activity, self-confidence level, sleep quality and quantity, mood, stress level) was implemented to further facilitate behavior change in the natural settings between the intervention sessions.

A screenshot of how the sessions look like within the Minddistrict platform can be seen in the appendix (Fig. A.2).

2.4.4. Control condition

Participants allocated to the control condition are only prompted to the pre-, mid- and post-intervention assessments as well as 6- and 12-months follow-up assessments. Furthermore, they will receive access to the prevention program by the end of the last follow-up assessment (about 12 months after baseline assessment).

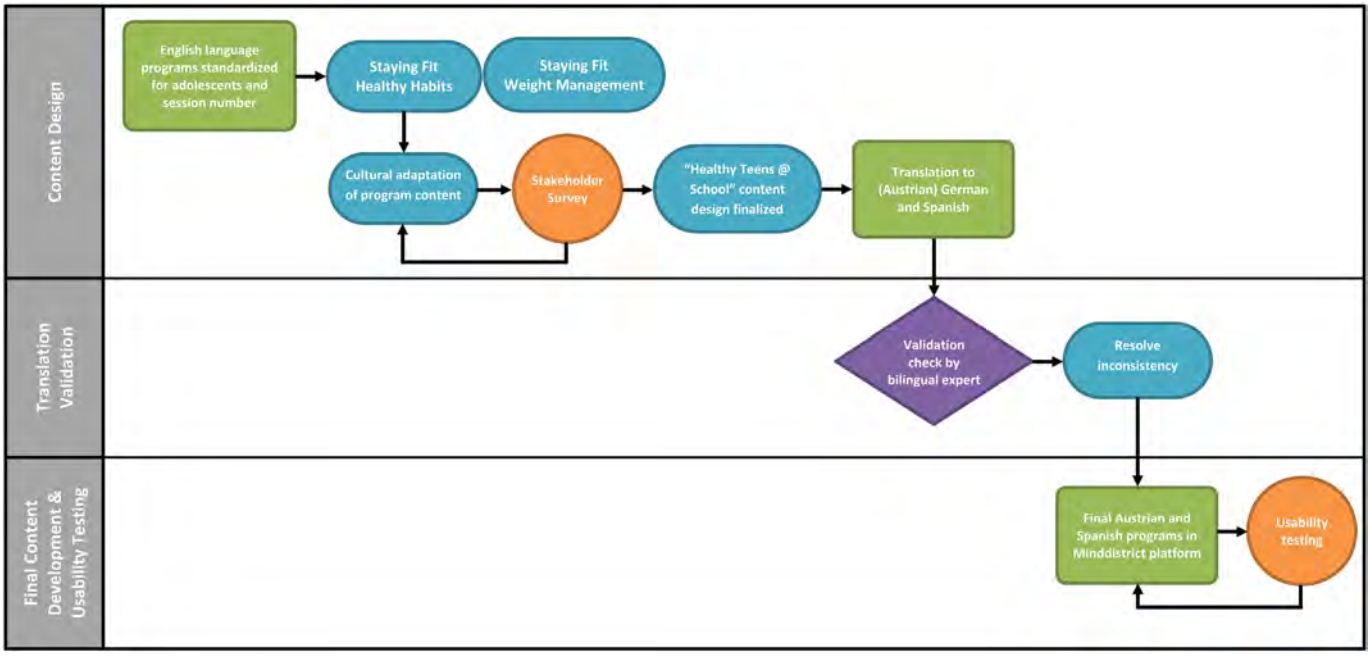

Fig. 2. Translation and adaptation process.

Table 1
Session themes and intervention components of the *Healthy Teens @ School* prevention program (the session themes of the original US versions of the StayingFit program are published in Jones et al. (2014)).

Session contents	
Session/week	Content/topics
1	Introduce program, describe good and bad reasons for healthy decisions, introduce diary
2	Establish nutritional intake needs based on the nutritional pyramid, introduce concept of appetite monitoring including eating in response to moderate hunger and fullness cues, describe relation between stress & eating, describe "red", "yellow" and "green" foods (only in WM track)
3	Introduce the importance of healthy exercise, describe relation of exercise and weight management (only in WM track), set healthy and realistic exercise goals using FITT (frequency, intensity, time and type of exercise) principle, developing healthy routines with regard to exercise and sleep, learn how to increase resilience to stress
4	Describe how to slow down eating and to recognize and reduce emotional eating (extended in WM track), provide a mindful eating exercise, educate how to reduce sedentary activities, providing tips for time management
5	Learning how not to participate in stigma about weight, ways to stay confident, strategies for dealing with stigma
6	Review concept of hunger/fullness monitoring, providing healthy options for snacks and food cravings, overcoming barriers to healthy eating, stress and social relationships, tips for increasing assertiveness (enhanced in HH track)
7	Environmental factors that influence eating and eating in "risky" situations (only in WM track), tips for eating in restaurants (only in WM track), discussing mood myths, why diets do not work and the negative effects of dieting, dealing with smartphone stress (only in HH track)
8	Body image, self-esteem, direct and indirect triggers of negative thoughts and feelings (extended in WM track), overcoming barriers to physical activity, learning how to reward yourself
9	Learn about eating disorders and how to get support (information regarding binge eating enhanced in WM track), learning about functions of emotions and how to deal with negative emotions and stressful thoughts, discriminating between helpful and unhelpful behaviors, practice how to focus on the positive
10	Learning how to respond to negative body image triggers, cognitive restructuring, feel-good body tips, maintaining health habits in the long run, looking back at whole program content
Goal setting	Participants are asked to set two specific goals at the end of each session with regard to the session topics. Goals are reviewed by the end of session 5 and 10.
Review quiz	A short quiz at the end of each session is implemented to briefly review the content of the session.
Diary	Participants are asked to complete a diary on a daily basis logging habits (food intake, physical activity, self-confidence level, sleep quality and quantity, stress level, mood), Smartphone App or PC
Feedback	Participants receive automatic personalized feedback after completing the baseline and follow-up assessments based on existing norm values (average, below average, above average) of the used questionnaires.

2.5. Assessment and data management

2.5.1. Data management and data protection issues

Data management and monitoring are provided by the Institute of Biostatistics and Clinical Research (Münster, Germany) for the whole consortium in order to maintain comparable high quality in the conduct of the ICare research projects in trial planning, data management, online monitoring, and analysis.

Since studies in human beings are performed, data protection and confidentiality issues are of great concern. Access to the data files is restricted to researchers and clinicians involved in the study. Staff involved is required to sign a confidentiality statement. After collection, data are pseudonymized at the local level, electronically encrypted and shared for study purpose only in aggregated form within the data management system. Appropriate measures are taken to prevent unauthorized use of study information. All studies that include the storage and use of personal data adhere to the following procedures: The project follows the relevant legislation in the countries participating in this project and any applicable EU legislation regarding data protection. Procedures for the collection and storage of personal data comply with relevant European regulations and directives, in particular with Directive 1995/46/CE on data protection, 1997/66/CE on the handling of personal information and Directive 2002/58/CE (on the same subject). The collected data is protected against any unauthorized access in accordance with current legal regulations.

Main points within the data protection plan are the rigorous encryption of participants' data for data transmission with state of the art methods, pseudonymization, maintenance of data integrity, and regulations for data access.

Besides the e-mail-address which might contain personal information (full name) and which is required for login at the platform, participants are never asked for any other personal information while completing the assessments and the prevention program. Therefore, platform data cannot be directly linked to the login information (e-mail address).

The data is introduced and analyzed by computers. As for Internet use, data protection systems were designed (using secure passwords, encryption, etc.). Only the authorized personnel have access to the database using a password. Data will be encrypted using recent strong like AES 256bit algorithms (Advanced Encryption Standard).

All potential personal information required during the trial for organizing follow-up assessment (e-mail-address used for login at the platform) will be destroyed at the end of the trial. The researchers in the study will not reveal data from which personal and health information about the participants could be deduced. The same principles will be taken into consideration in the dissemination of data in the publication of scientific papers and the presentation of research reports at scientific conferences.

Data entered into the Minddistrict platform is saved at a secured server of the Minddistrict company. Data from different study sites and countries will be aggregated and initially processed by the Institute of Biostatistics and Clinical Research (Münster, Germany). Only pseudonymized datasets will be further provided to the local research teams for further analyses and publications.

2.5.2. Assessment

Assessment is conducted at pre- and post-intervention (T_1 & T_2), and at 6- and 12-months (T_3 & T_4) after T_1 (online-assessments). Additionally, a short assessment 6 weeks after T_1 is conducted to assess potential mediators of intervention outcomes (T_M). Table 2 gives an overview of instruments that are used at the different time points. The completion of the questionnaires lasts approximately 30 min.

2.5.3. Adverse events

Unexpected negative effects of the intervention are evaluated. The following negative events are monitored continuously during the trial phase:

- Breaches of confidentiality (contacting parents due to severe mental health conditions)
- Suicidal thoughts and ideations
- Any negative events targeting the physical and mental health of participants reported by class teachers

Table 2
Instruments used in the Healthy Teens @ School trial and measurement time points.

Instrument	Abbrev.	Aim/domain	Purpose	Measurement time points				
				T_1	T_M	T_2	T_3	T_4
Intuitive eating scale – 2 (Tylka and Kroon Van Diest, 2013)	IES-2	Intuitive eating	PO	x		x	x	x
Eating disorders examination-questionnaire (Hilbert et al., 2007)	EDE-Q	Eating disorder symptomatology	SCR, SO	x		x	x	x
Weight concerns scale (Killen et al., 1994) - females Male body image concerns scale – males (Weisman et al., 2014)	WCS MBICS	Body image	SO	x		x	x	x
Body mass index	BMI	Weight status	SCR, SO	x		x	x	x
Child depression inventory (Kovacs, 2004)	CDI	Depression	SO, MOD	x	x	x	x	x
State & trait anxiety inventory (Spielberger, 2010)	STAI	Trait anxiety	MOD, MED, SO	x	x	x	x	x
Food frequency questionnaire (adapted from Truthmann et al., 2011)	FFQ	Fruit and vegetable consumption	SO	x		x	x	x
international physical activity scale – adolescents (Hagströmer et al., 2008)	IPAQ-A	Physical activity, sedentary activities	SO	x		x	x	x
KIDCOPE (Spirito et al., 1988)	KIDCOPE	Stress coping	SO	x		x		
Credibility & expectancy questionnaire (adapted for online interventions from Devilly and Borkovec, 2000)[a]	CEQ	Participants expectancy and motivation	MOD, SO	x				
Rosenberg self-esteem scale (Rosenberg, 1965)	RSE	Self-esteem	MOD, MED, SO	x	x	x	x	x
Alcohol use test (Bohn et al., 1995)	AUDIT-C	Alcohol consumption/misuse	MOD, MED, SO	x	x	x	x	x
Inventory of life quality in children and adolescents (Mattejat and Remschmidt, 2006)	ILC	Health-related quality of life	SO	x		x	x	x
Working alliance inventory SR (adapted)[a] (Hatcher and Gillaspy, 2006)	WAI-SR	Satisfaction with treatment	MED		x			
Client satisfaction questionnaire (adapted for online interventions from Attkisson and Greenfield, 2004)	CSQ	Satisfaction with treatment	SO			x		
Client service receipt inventory (Beecham and Knapp, 2001)	CSRI	Economic evaluation	ECO	x		x	x	x
Platform meta-data		Adherence and engagement	MOD, MED		+			
Sociodemographic information		Sex, age, level of education, migration background, household size, relationship status, place of residence, school type, school grade, diagnosed mental disorders and treatments	MOD	x				

Abbreviations: PO = primary outcome, SO = secondary outcome, SCR = screening for eating disorders, MOD = moderator, MED = mediator, ECO = economic evaluation; + assessed automatically on the platform during the whole intervention phase; T_1 = baseline, T_M = Mid Intervention, T_2 = post-intervention, T_3 = follow-up 6 months, T_4 = follow-up 12 months.

[a] In intervention group only.

The following negative events are evaluated at the post-intervention assessment (T_2) only:

- Self-reported worsening in healthy lifestyle due to the program as assessed by one item of the Client Satisfaction Questionnaire (CSQ)
- Any self-reported negative side-effects experienced during the program phase

The following negative events are evaluated at the post intervention assessment (T_2) and follow-ups (T_3, T_4) and defined as adverse event if not present at baseline-assessment:

- Severe depression (CDI total score ≥ 18)
- Alcohol abuse (AUDIT-C total score ≥ 6)
- Extreme dieting (EDE-Q restraint score ≥ 3.02)
- Use of weight-loss products at least once a week (EDE-Q item 17 ≥ 4)
- Excessive exercise at least once a week (EDE-Q item 18 ≥ 4)
- Exercise-related injuries as obtained by the CSRI
- Self-reported onset of a clinical eating disorder

2.6. Outcomes

The primary outcome is change on the Intuitive Eating Scale-2 (IES-2; Tylka and Kroon Van Diest, 2013). Secondary outcomes are: eating disorder psychopathology, body image concerns, body mass index, food intake, physical activity, depression, anxiety, self-esteem and stress coping. All questionnaires and their role (primary outcome, secondary outcome, moderator/mediator) are listed in Table 2.

2.7. Statistical methods

Randomization is controlled by appropriate statistical tests on the baseline variables. The study collective will be characterized by descriptive statistical methods such as relative and absolute frequencies, mean, median, standard deviation, and inter-quartile-range (IQR) and appropriate graphics such as histograms, boxplots, and bar charts. The intra-class-correlation will be calculated to control for the assumptions made for the power calculations. Assumptions for the appropriate statistical tests will be checked for normality by histograms, skewness, and Kolmogorov-Smirnoff test, sphericity will be assessed through Mauchly test, and the assumption of equality of variance-covariance matrices through Box test and Levene test.

For the primary endpoint (difference in IES-2) the two arms online-intervention (I) and control condition (C) will be compared using a two sided two-sample *t*-test whereby the *t*-test will be adjusted for clustering according to Hedges (2007). The primary analysis will be performed on the intention-to-treat (ITT) collective. The results of the primary and secondary analyses will be presented by appropriate effect estimates and 95% confidence intervals. Additional sensitivity analyses of the primary analysis will be conducted. The primary analysis will be repeated using a generalized linear mixed model (GLMM). Baseline variables that showed a significant difference between the two study arms will be included in the model. The cluster variable will be considered as random effect. Also study center will be included in the model.

The secondary outcomes will be analyzed by a GLMM for longitudinal repeated measurements to evaluate the effectiveness of the intervention on the measured outcome variables among those who completed post-intervention assessments. Covariables will be included in the multivariable statistical models to control for confounding.

Missing values are expected to occur in the study data due to the online setting of the trial. A substantial study dropout is very likely to occur at all times, especially at the later measurement times T_3 and T_4. The study was planned to recruit additional participants to cope with power losses due to missing values. Thus, we expect the number of completers at the primary endpoint to be sufficient to perform the primary analysis without imputation of the data. However, missing data can still be problematic and lead to bias. Within the secondary analyses of the data generalized linear mixed models (GLMM) will be used, such that missing values do not lead to an exclusion of these participants from the analyses. Also, multiple imputation will be performed on the analyzable dataset and the primary analysis will be repeated. The imputation strategy will be developed in the blinded review of the data.

2.7.1. Moderator and mediator analyses

Moderator and mediator analyses will be conducted within a separate work package of the ICare project.

2.7.2. Cost-effectiveness analyses

Cost-effectiveness analyses will be conducted by the London School of Economics and Political Science within a separate work package of the ICare project.

2.8. Sample size calculation

For this trial, we use an adaptive group-sequential design with one interim analysis. For the calculation of the sample size we determine a reasonable and feasible sample size in a classic design and, subsequently, embed this design in the adaptive group sequential design.

We will test the null-hypothesis (H_0) that the mean differences (T_1-T_2) of score on the Intuitive Eating Scale (IES) are the same in the intervention group compared to the control group.

Primary hypothesis: $M_i : Mean(\text{IntuitiveEatingScale}(IES)_{t1} - IES_{t2})$

H_0: $M_{ICare-HT@S} = M_{Control}$ $\quad H_1$: $M_{ICare-HT@S} \neq M_{Control}$

For the primary endpoint, difference in intuitive eating score, the two arms online-intervention and control group will be compared using a two-sided two-sample *t*-test, assuming normal distribution of the differences in IES within each group. The estimation of a reasonable sample size is based on the smallest relevant effect. Since the trial is cluster randomized we correct the total sample size N by the design effect $DE = 1 + (m - 1) * \rho$, with m as average size of clusters and ρ, the intra-class correlation (ICC; Eldridge et al., 2006). For this study we assume a mean cluster size of 60 pupils per school and an ICC of 0.02. The design effect calculates as DE = 2.18. The necessary sample size N′ is acquired by multiplying N with DE, i.e. $N' = N * DE$. Additionally, we will adjust the sample size for a 30% fdrop out rate. For all calculations we assume a significance level of $\alpha = 0.05$ and a power of $1 - \beta = 0.8$.

To reach a sufficient level of representativity a minimum of 7 schools will be included in the study. Assuming an effect size of d = 0.5 and accounting for a 30% dropout rate we would need to recruit 400 pupils to the trial.

The confirmative question in this trial will be answered in the framework of an adaptive sequential design based on a group sequential plan according to Wang and Tsiatis (1987) (Optimum Delta design with minimized average sample size under the alternative hypothesis, Delta = 0.41, no stop for futility) with one interim analysis, a global significance level of 5% and a power of 80%. We expect to identify a relevant effect of at least d = 0.5. Compared to the one-stage fixed design the adaptive design requires additional 30 pupils to be recruited to the study. Thus, we aim to recruit a total of 430 participants in 7–8 schools.

Resulting from these considerations, the interim analysis is performed after the assessment of the primary outcome of 150 participants (75 per group, information rate 0.5, power 42.2%), which is expected to be reached after approximately 11 months. The purpose of this interim analysis is to allow for sample size recalculation applying the Inverse Normal method (Lehmacher and Wassmer, 1999). If no sample size adjustment is deemed necessary, the final analysis is performed after the primary outcome of, in total, 300 pupils have been completely observed with regard to the primary outcome across both groups.

All calculations were performed using the ADDPLAN Software (Version 6.0.9).

3. Discussion

In this study protocol we describe the study design and methodology of a multi-country cluster randomized-controlled trial investigating the effectiveness of a transdiagnostic prevention program called “Healthy Teens @ School” aiming at reducing eating disorder and obesity risk.

A number of strengths and limitations to this study have to be taken into consideration. Strengths involve the randomized controlled study design and 6 and 12-months follow-up to assess the short- and long-term effects of the intervention. The content was adapted from an existing intervention developed in the USA and culturally adapted for Europe. The original intervention (StayingFit) has been evaluated in previous studies and the “Healthy Habits” track has been proven to be effective for reducing disordered eating behaviors, increasing fruit and vegetable consumption and physical activity, and for improving body image in a subset of students with elevated weight and shape concerns. The “Weight Management” track has been proven to support weight loss, reduce binge eating, and improve weight and shape concerns in at-risk for overweight and overweight adolescents (Jones et al., 2014). Different stakeholder groups and representatives of the target group (adolescents aged 14–19) were involved in the adaptation process of the prevention program which can be mentioned as an important strength and should contribute to a proper implementation of the study. Remarks from health care professionals such as school physicians and school psychologists were considered as well as ideas and comments from teachers. Adolescents were able to bring their own ideas in focus group discussions. In a final step, the usability of the program components and platform function were tested in a usability study and the program was adapted accordingly.

The online mode of delivery is an additional strength as Internet-based programs are known to be attractive and acceptable for adolescents (e.g., Boydell et al., 2014; Das et al., 2016; Mangunkusumo et al., 2007). Furthermore, if our program turns out effective, it would be easy to translate it to other languages and to disseminate the program to other European countries. A detailed statistical analysis plan has been set up and state-of-the-art methods will be used to deal with missing data. As part of the larger ICare project this RCT will determine how an adapted version of StayingFit is disseminated within Europe. Also, an economic evaluation (cost-effectiveness) and a mediator- and moderator analysis will be included. Furthermore, this study will be conducted in routine school days. Thus, the results from this study will shed light on the feasibility of implementing online prevention programs in school routine in European countries and add to the understanding of how to address eating and weight related problems in adolescents through a prevention program implemented unobtrusively in their ordinary school day. Reaching adolescents in schools democratizes access to prevention programs, can avoid stigmatization and reduce health inequalities.

However, the study also has several challenges and limitations. First, since schools will not be randomly selected from all schools in Austria and Spain external validity may be limited, because participating schools might not be a representative sample of the Austrian and Spanish population. Second, in the current stage of the project, the prevention program is only available in German and Spanish. Adolescents with limited German or Spanish language skills such as migrants might therefore be underrepresented in the sample. Third, participating in the study is quite time-consuming for the intervention schools. Schools have to provide four lessons for the assessments, and additional five for the program itself. This might be a hindering factor for adoption and implementation. Finally, adherence represents a major challenge in internet interventions in general. To maintain adherence, we have scheduled a number of e-mail reminders throughout this trial.

4. Conclusion

We present the design of our study aimed at preventing obesity and eating disorders among adolescents. If the Healthy Teens @ School program is shown to be effective, it can be disseminated as part of the larger ICare dissemination initiative which seeks to expand access to online mental health programs across Europe. It will also add to the knowledge base about effective means of preventing both eating disorders and obesity.

Trial status

Recruitment started in February 2017 in Austria and will continue approximately through March 2018. Follow-up assessments for the remaining patients are expected to be completed by March 2019.

Competing interests

The authors declare that they have no competing interests.

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Author contributions

MJB, KW, MN, and MZ designed the study. DG contributed significantly to the study design. MJB wrote the first draft of the manuscript. KW, MZ, SK, RH, DG, MN and CJ revised the manuscript and completed the final draft. All authors read and approved the final manuscript.

Ethical statement

This trial is conducted in compliance with the protocol, the Declaration of Helsinki and good clinical practice. The trial was registered at ISRCTN (ISRCTN51957280). The local ethical commissions in each country provided approval. Data security/confidentiality is guaranteed; all relevant EU legislation and international texts on privacy are observed and respected. Regarding regulation at international level, starting from the OECD guidelines including the “Guidelines on the protection of privacy and transborder flow of personal data” (1981) and “Guidelines for the security of information systems” (1991/92), the ICare consortium in particular acknowledges heterogeneity in international data protection jurisdiction.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.invent.2018.02.007.

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