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Evaluation of an innovative family-centred care and prevention intervention for children with overweight and obesity: a mixed-methods study protocol of the randomised controlled fruehstArt study in Germany

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ABSTRACT

Introduction Childhood overweight and obesity pose a growing public health problem with increasing prevalence both in Europe and globally. Reasons can be found in behavioural factors such as a sedentary lifestyle, eating habits or low exercise levels and to a lesser extent in a genetic predisposition or a metabolic disorder. Preventing children with obesity and overweight to grow into obese teenagers is therefore of high importance. However, there are currently no established care and prevention programmes in Germany for the early reduction of overweight and prevention of obesity in children aged 3–6 years. fruehstArt aims to close this gap with a cross-sector outreach and family-centred personal counselling approach, where parents receive support from paediatricians and trained coaches who conduct consultations in the home of the family. The main research question is whether the fruehstArt programme reduces overweight and obesity in children aged 3–6 years within 12 months, as measured by the body mass index-standard deviation score (BMI-SDS).

Methods and analysis fruehstArt has been developed as a new form of care, which includes a family intervention with motivational interviews provided by paediatricians and individual home-based counselling provided by a trained coach on eating behaviour, exercising, sleeping behaviour and age-appropriate use of electronic devices. fruehstArt will be accompanied by an efficacy study (summative evaluation of change in BMI-SDS). In addition to German, the project is also offered in Turkish in order to reach families with a migration background and language barriers. 812 children with overweight or obesity and their families in the region North Rhine will be included and observed over 12 months. Recruitment of children occurred from December 2023 to April 2025 with the final visits scheduled for April 2026. The study is conducted as a randomised controlled trial with a social-ecological intervention approach, considering children in their living environment and conditions. Moreover, a

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The mixed-methods approach (qualitative and quantitative data) allows a multidimensional view on the quality and effectiveness of the fruehstArt programme.
⇒ The programme focuses on outreach counselling, digital support (e-health & apps) and targeted cultural and linguistic adaptations in order to effectively reach and involve families with a migrant background in particular.
⇒ The programme combines services provided by statutory health insurance funds, the German pension insurance scheme and municipal structures into an innovative, cross-institutional model that effectively combines behavioural and situational prevention measures.
⇒ Recruiting paediatricians, affected families and, in particular, Turkish-speaking children is a key challenge—despite targeted measures such as the integration of local services (e.g. neighbourhood mothers) and motivational public relations work.
⇒ The high organisational effort required in medical practices, including the training of medical assistants and complex recruitment procedures, necessitates intensive coordination and continuous communication.

formative evaluation at the process level, and the system level will be carried out and complemented by a health economic analysis. Those are carried out to provide information about the intervention's success and relevant costs. Thus, fruehstArt is realised in the form of an effectiveness–implementation hybrid design that combines the analysis of effectiveness with an evaluation of the implementation process.

Ethics and dissemination The study received ethics approval in a coordinated procedure from the ethics committee of the Medical Faculty University hospital of Cologne and the ethics committee of the North Rhine Medical Association. For all collected data, the relevant national and European data protection regulations will be considered. All personal data (contact details) will be removed for the data analysis in order to ensure pseudonymisation. Dissemination strategies include reports and quality workshops for organisations, peer-reviewed publications and the presentation of results at conferences.

Discussion The aim of the unique form of care fruehstArt is to improve the care of preschool children with overweight or obesity through innovative home-based counselling, cross-sectoral service integration and to address the cultural needs of Turkish families.

Trial registration number DRKS00030749 (29-09-2023)

INTRODUCTION

In Germany, almost 11% of all girls and over 7% of all boys aged 3–6 years have a body mass index (BMI) above the 90th percentile (BMI>P90) and are therefore considered overweight. In the same age group, 3% of girls and 1% of boys are already obese (BMI above the 97th percentile). By the age of 13 years, the prevalence rises to 20% (obesity: 7%) and 21% (obesity: 8%), respectively.[1] Internationally, childhood overweight and obesity are commonly defined using the International Obesity Task Force (IOTF) guidelines,[2] which establish age-specific and sex-specific cut-offs corresponding to adult BMI values of 25 kg/m^2 (overweight) and 30 kg/m^2 (obesity). In the German healthcare system, however, clinical practice relies on national reference percentiles. Therefore, in this study, overweight is defined as a BMI above the 90th percentile (>P90) and obesity as above the 97th percentile (>P97) of the German reference population, which aligns with the recruitment criteria for our intervention. In addition to lifestyle, important causes are family, social, genetic and environmental factors (e.g. weight and education of parents, availability of community services).[3] If children are already overweight at an early age, the risk of further weight gain increases during adolescence.[4 5] Overweight may lead to a number of chronic diseases such as cardiometabolic comorbidities, orthopaedic disorders and psychosocial problems.[5 6] In addition, the risk of developing mental disorders such as depression and eating disorders increases, which might have a negative impact on educational functioning, attainment success and increased healthcare costs.[5 7 8] Lifestyle and behaviour changes may help to develop and maintain a healthy weight and help to prevent or reduce consequential diseases and complications. However, to be effective, it is important that lifestyle changes are implemented as early as possible in the lifespan, are of high intensity, involve parents and paediatricians, are context-sensitive and take into account additional counselling measures, for example, in the form of outreach coaching.[9 10]

Currently, there are no nationwide established care and prevention or outpatient (cross-sectoral) and family-centred rehabilitation programmes for the early reduction of overweight (BMI>P90) and the prevention of obesity (BMI>P97) in children aged 3–6 years in Germany. The preschool and low-threshold, cross-sectoral, outreach and family-centred overweight and obesity prevention, called fruehstArt, aims to close this gap. It combines a newly developed home-based counselling service carried out by trained coaches and a supporting e-health platform and web app with existing statutory health insurance (SHI) financed offers and offers from cities/municipalities. Besides German-speaking families, it specifically addresses families with a Turkish migration background and thus stands out from other projects that are offered in multiple languages but do not include any intervention, e.g. health promotion and obesity prevention in paediatric practice. Furthermore, already established structures (such as the Cologne neighbourhood mothers: trained women with a corresponding cultural background who provide the coaches with access to the community and support them in their work as required) are integrated into the fruehstArt project. This creates a new form of cross-sectoral care that combines behavioural and community support measures.

The new form of care fruehstArt will be accompanied by an efficacy study to evaluate the project's goal of reducing overweight or obesity in children aged 3–6 years by changing everyday lifestyle habits. To gain a comprehensive understanding of the intervention (including the implementation process), its determinants of adoption and the costs or types of costs that are relevant for its success, a complex process evaluation and a health economic analysis will be carried out. The complex process evaluation is divided into a formative evaluation, which accompanies the intervention during implementation (i.e. at the process level), and a formative evaluation at the system level, which focuses on all practising outpatient paediatricians who potentially implement the new form of care in the long term. Due to the study goal of transferring the intervention to standard care in the long term after successful evaluation, translation into everyday care must already be taken into account in the study setting (translation type 2).[11] Therefore, the formative evaluation (process and system level) is important to identify possible obstacles and implementation factors on the part of the paediatricians. Capturing a more comprehensive picture makes it possible to adjust the intervention during the research process or to develop recommendations for use in standard care.

Aims and research questions of fruehstArt

The goal of the correspondent study is to evaluate the fruehstArt programme by answering the following research questions. The primary outcome will be assessed at

baseline (enrolment, T0), after 4 months, after 8 months and after 12 months (T2). The secondary outcomes, with the exception of motor skills, will be assessed at baseline, after 6 months (T1) and after 12 months (T2). Motor skills will be assessed only at baseline and after 12 months. Further details on the measurement procedures are available in the Statistical Analysis Plan (SAP, German language), which is attached as online supplemental file 1.

Primary research question (summative evaluation):

- Does fruehstArt lead to a reduction in overweight and obesity in children aged 3–6 years after 12 months as measured by the change in BMI-SDS (12 months (T2) to baseline (T0)) in the intervention group (IG) compared with the control group (CG)?

Secondary research questions

summative evaluation:

- Does fruehstArt lead to more physical activity, a healthier eating behaviour, healthier sleeping habits and less media consumption among IG children compared with the CG?
- Does fruehstArt lead to an improvement in nutritional practices for parents in the IG compared with the CG?
- Does fruehstArt lead to an improvement of motor skills in IG children compared with the CG?
- Does fruehstArt lead to an improvement of the quality of life for parents in the IG compared with the CG?
- Does fruehstArt lead to an increasing health literacy among parents in the IG compared with the CG?
- What factors facilitate or hinder the implementation of the intervention components?
- What is the quality of implementation of fruehstArt and what differences can be observed between the families?
- Does implementation quality influence the effectiveness of the fruehstArt intervention?
- What is the potential utilisation of frühstArt from the perspective of outpatient paediatricians?
- What barriers and facilitating factors do outpatient paediatricians perceive for the long-term implementation of frühstArt into standard care (including regional specificities)

formative evaluation (process and system level):

- What factors facilitate or hinder the implementation of the intervention components?
- What is the quality of implementation of fruehstArt and what differences can be observed between the families?
- Does implementation quality influence the effectiveness of the fruehstArt intervention?
- What is the potential utilisation of fruehstArt from the perspective of outpatient paediatricians?
- What barriers and facilitating factors do outpatient paediatricians perceive for the long-term implementation of fruehstArt into standard care (including regional specificities)

METHODS AND ANALYSIS

Study design

fruehstArt implements early, cross-sectoral, outreach and family-centred overweight or obesity prevention via home-based counselling sessions with trained coaches. The Federal Joint Committee is funding the project over a period of 48 months. During this period, 812 children with overweight and their parents or legal guardians in the catchment areas (Cologne, Bonn, Moenchengladbach, Dueren, Oberhausen, Sankt Augustin and Neuss) of seven obesity centres in the North Rhine area will be included in the study and recruited in paediatric practices and obesity centres participating in the project. Recruitment started in December 2023 ('first-child-in') and ended in April 2025 ('last-child-in'). The last visit ('last child out') is scheduled for April 2026, followed by data processing and analysis, including reporting to the sponsor by September 2026 and subsequent publication of the results. In order to reach families with a migration background, fruehstArt is also offered in Turkish (including the coaching in some regions and all programme materials for families). All children aged 3–6 years and their families can be enrolled if the inclusion criteria listed in table 1 are met.

The study will be conducted as a randomised controlled trial and each family participating in the study will be observed over a period of 12 months. Randomisation will be carried out at the level of the individual child, stratified by language (German/Turkish) and gender, in a ratio of 2:1 (intervention:control) via the 24/7 Internet service ALEA (ALEA Clinical by FormsVision, Abcoude, NL) based on permuted blocks of variable length. Therefore, the randomisation can take place directly in the paediatric practices (see figure 1). As a summative evaluator in the project, the Institute of Medical Statistics and Computational Biology (IMSB) offers support for questions or problems with ALEA.

fruehstArt is realised in the form of an effectiveness–implementation hybrid design, specifically classified as a hybrid type 1 design according to the framework proposed by Curran *et al*.[12] In line with this design, the primary focus is on testing the clinical effectiveness of the intervention compared with standard care at patient level. At the same time, an assessment of the implementation of the intervention at system level and of the processes at patient and service provider level will be carried out.[12] The evaluation with this specific design is tailored for the social–ecological intervention approach used in the project, which considers children and their behaviour in relation to their social living environment and living conditions.[12 13] The approach also considers factors influencing overweight and obesity at the level of the children, their family, their social, cultural and community environment as well as the level of the respective healthcare system. This combines an implementation strategy for system-level providers and an intervention for children and their families (structural care innovation) for behavioural and structural prevention. The study

Table 1 Inclusion and exclusion criteria

Inclusion criteria		Exclusion criteria
The child is overweight (BMI: >P90 to ≤P97) or obese (>P97, ICD E66†)*	**OR** A sudden weight gain with a BMI-SDS increase of 0.2/year is detected, which is classified as a cause for concern by the paediatrician	Overweight of the child results from medical reasons
AND		**AND/OR**
The child is insured by SHI‡ companies		The child is not insured by SHI companies
AND		**AND/OR**
Sufficient language skills in German or Turkish on the part of the parents/guardians		Participation in the study is too much of a (psychological/psychosocial) burden from the family's point of view
AND		**AND/OR**
Parents/guardians have given their written consent to participate in the study		Parents/guardians do not have sufficient language skills in German or Turkish
		AND/OR
		Parents/guardians have not given their written consent to participate in the study

*P=percentile.
† ICD, E66= International classification of diseases, Obesity
‡ SHI = statutory health insurance
BMI-SDS, body mass index-standard deviation score.

description follows the attached Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2025 checklist (online supplemental file 2).

Study procedure components and data collection

Figure 1 provides an overview of the individual study components and the timeline for the fruehstArt intervention and the CG. During the 12-month study period, the IG receives a motivational interview provided by the paediatrician every 4 months. Additionally, they receive outreach counselling from specially trained coaches (e.g. social education workers, sports scientists or psychological psychotherapists). They also use the fruehstArt web application (web-app) to complete the study questionnaires. The web app offers them additional features, such as setting and monitoring behavioural goals, practical tips for a health-promoting lifestyle, access to cooking recipes and the opportunity to exchange information with the coach.

The questionnaires will be answered by the parents at a total of up to three time points (baseline (T0), 6 (T1) and 12 months (T2) after inclusion in the study) (see table 2 and supplement 3). Detailed information on the fruehstArt-intervention is given in the Coaching intervention section (see also figure 2).

For children with a BMI above the 97th percentile, the paediatrician can also prescribe rehabilitation programmes from the German Pension Insurance (DRV). A distinction is made between existing inpatient rehabilitation programmes and the outpatient rehabilitation programme developed for the fruehstArt project (fruehstArt rehab), which is initially only available to children in the IG, but the DRV has expressed the intention to provide this intervention as routine care service after

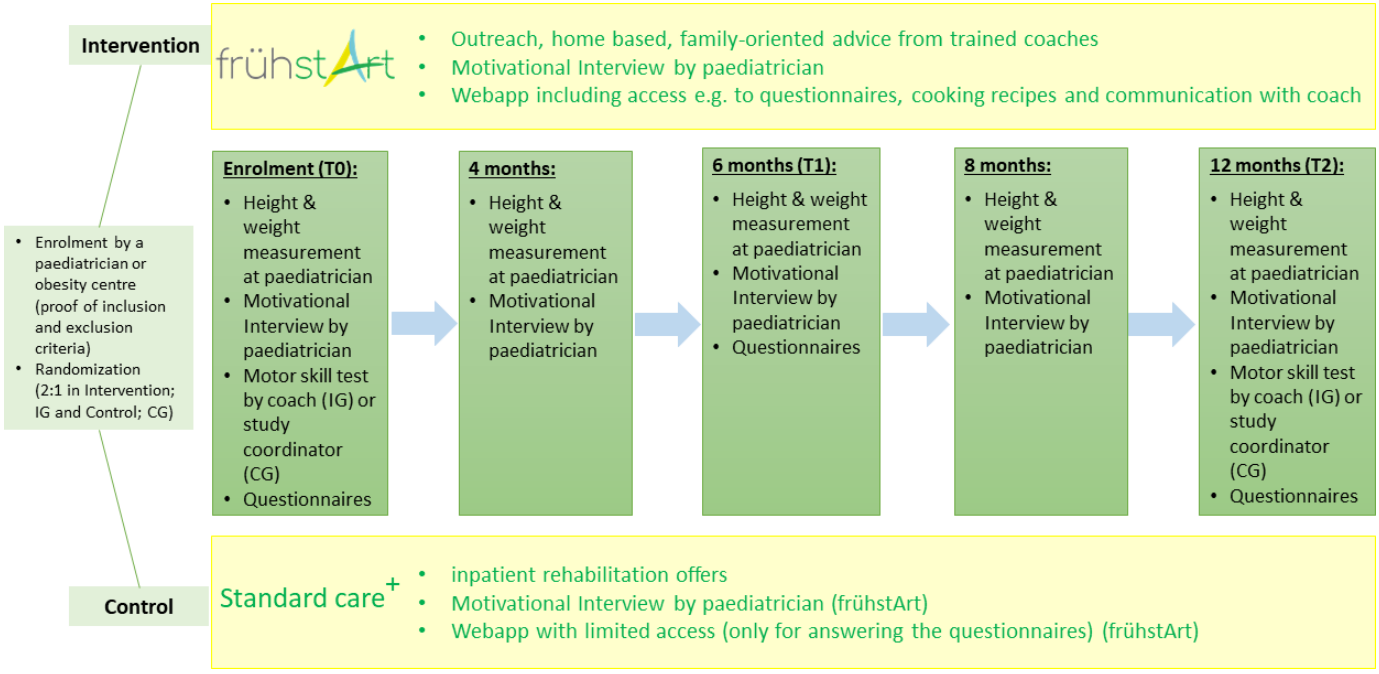

Figure 1 Overview of the components and timeline of the study.

Table 2 Questionnaires used in fruehstArt

Questionnaire instruments*	Short description
Children's Health Interventional Trial (CHILT) (modified version)[38]	► measures general socio-demographic characteristics of all family members (child, mother/guardian, father/guardian) (T0), children's physical activity, media consumption (time) and sleep behaviour (T0, T1, T2) and the parents' level of physical activity and average sitting time (T0, T1, T2)
Food frequency questionnaire (FFQ)[39 40]	► records the frequency of consumption and portion sizes of 54 food categories (T0, T1, T2)
Comprehensive Feeding Practices Questionnaire (CFPQ)[41]	► assesses various parental practices about their children's nutrition (T0, T1, T2)
ICEpop CAPability measure for Adults (ICECAP-A)[42]	► measures quality of life (Qol) in adults (T0, T1, T2)
Parental Health Literacy (PHL); (developed by members of the University of Potsdam, Faculty of Human Science, Department Sports and Health Sciences (former Department of Health Sciences, Fulda University of Applied Sciences))[43]	► measures specific parental health literacy (T0, T1, T2)
Questionnaire for children and adolescents to record health-related quality of life (KINDL^{R})[44]	► measures health-related quality of life in children with outpatient rehabilitation (timepoints: start/end of outpatient rehabilitation)

*Detailed information on all used questionnaire instruments can be found in online supplemental file 3.

positive evaluation. Outpatient rehabilitation takes place in facilities close to the children's home for 6 months, two times a week for 90 min in the form of group and individual appointments. For inpatient rehabilitation, a facility in Germany is selected in collaboration with the treating paediatrician. The typical duration of the programme is 4 weeks, during which all participants reside on-site and receive meals and lodging. Both the outpatient and inpatient rehabilitation programmes focus on nutrition, exercise, relaxation and a healthy lifestyle for the child. For the evaluation, rehabilitation is documented by the doctor as a recommendation, and the coaches also document whether rehabilitation took place and what type of rehabilitation was carried out. This is also reflected in the assigned strand (see figure 2). Depending on the type of rehabilitation, the coaches also document additional information at the end of the intervention, for example, how many days the family participated in rehabilitation.

The CG receives a motivational interview provided by the paediatrician every 4 months, the current standard of care and an adapted version of the fruehstArt web application for the sole purpose to fill out the study questionnaires (see table 2).

In both groups, weight and height measurements are taken quarterly (at baseline (T0), after 4 months, after 8 months and after 12 months (T2)) by the paediatrician using calibrated scales and stadiometers for the primary research question of the study (change in BMI-SDS). In addition, a motor skill test (jumping back and forth sideways), as part of the KiMo (*Kindergarten Mobil*), is carried out by the coaches and study coordinators in both groups at the beginning (T0) and after 12 months (T2) at the families' place of residence.[14 15] The fruehstArt coaches and study coordinators are trained in conducting the test before recruitment begins.

All data of the components described above will be collected within the study-specific eHealth-Platform to answer the primary and secondary research questions. The platform will be developed and designed by the Fraunhofer Institute for Applied Information Technology (FIT) in consultation with the consortium partners and potential users. To enable task-specific use of the platform, various visualisation applications (web-apps) are created. One application is designed for the participating paediatrician practices and the obesity centres to document the measurement data of the children. Another application is created for the coaches to document the counselling sessions and motor skills in the IG. Furthermore, there is an application for the study coordinators to document revocations of study participation and the results of motor skills test in the CG. Finally, there is an application for the participating families to answer the questionnaires (IG and CG), to access additional functions such as access to cooking recipes or the opportunity to exchange information with the coach (IG). The applications are implemented as responsive web applications and work in various web browsers (such as Chrome, Edge, Firefox). The applications also run on mobile devices such as smartphones or tablets.

Coaching intervention

The central component and innovative intervention of fruehstArt are the coaching sessions for the families of the IG that take place at the families' home. In addition to their professional expertise, the coaches are trained using a curriculum specially developed for the project, so that they can respond to the individual needs of the families during the home visits. The approximately 100-hour curriculum includes topics such as encouraging more physical activity, that is, outdoor play or a more active lifestyle, healthier eating and sleeping behaviour and reducing media consumption, as this is the focus of the coaching sessions. The training was developed by the German Sport University Cologne (DSHS), the Institute for Social Work (ISA e.V.) and the Academy of Public Health (AÖGW) based on the guidelines of the Working Group on Obesity in Children and Adolescents of the German Obesity Society (AGA) and the manual of the Consensus group on obesity training for children and adolescents (KGAS). Figure 2 provides an overview of the process of the

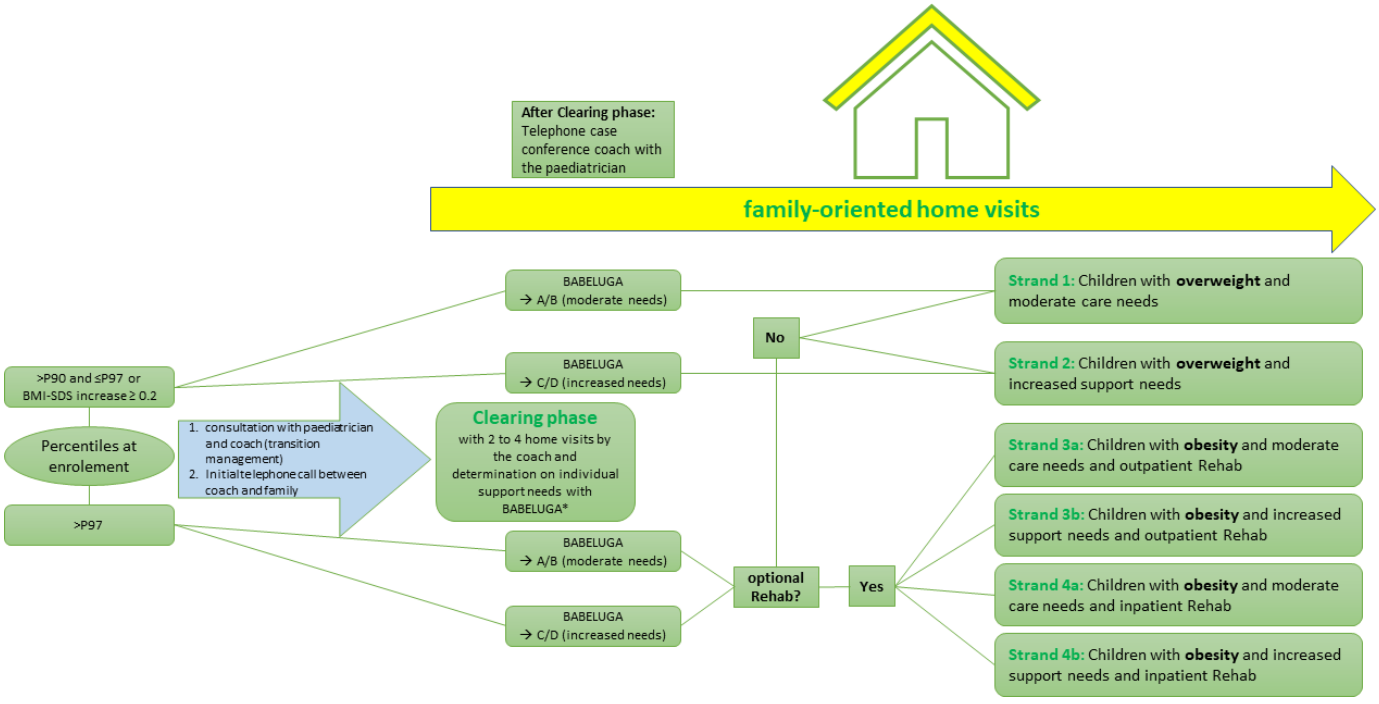

Figure 2 Process for determining support needs and course of the coaching intervention. (BMI-SDS, body mass index-standard deviation score; BABELUGA, Berliner - Obesity therapy programme for children, adolescents and their families - Exercise, counselling, support - Eating and drinking, personal initiative - Learning, quality of life - Family support - Group therapy for children and parents - Obesity diagnosis, long-term weight loss)

coaching intervention. After enrolment and determination of the BMI percentile or increase in BMI-SDS in the paediatrician's practice, transition management takes place between the coach assigned to the family and the paediatrician. The coach then contacts the family by telephone to plan the first home visit. Every coach is responsible for a specific catchment area around the obesity centres. In the first two to four coaching sessions (clearing phase), the individual support needs of each family in the IG are determined and categorised into moderate (BABELUGA A/B) or increased (BABELUGA C/D) support needs (BABELUGA, Berliner—Obesity therapy programme for children, adolescents and their families—Exercise, counselling, support—Eating and drinking, personal initiative—Learning, quality of life—Family support—Group therapy for children and parents—Obesity diagnosis, long-term weight loss).

A special risk assessment tool for overweight and obesity BABELUGA is used for this purpose.[16] Depending on the BMI percentile or BMI-SDS increase and the individual need for support according to BABELUGA as well as the receipt of a rehabilitation programme, the child and its family then receive one

Table 3 Description of coaching strands with number of follow-up visits

	Strand 1a	Strand 2a	Strand 3a	Strand 3b	Strand 4a	Strand 4b
Strand description	Children with overweight (>P90 and ≤P97)† and moderate care needs (BABELUGA* A/B)	Children with overweight (>P90 and ≤P97) and increased support needs (BABELUGA C/D)	Children with obesity (>P97) and moderate care needs (BABELUGA A/B) and outpatient rehabilitation	Children with obesity (>P97) and increased support needs (BABELUGA C/D) and outpatient rehabilitation	Children with obesity (>P97) and moderate care needs (BABELUGA A/B) and inpatient rehabilitation	Children with obesity (>P97) and increased support needs (BABELUGA C/D) and inpatient rehabilitation
Clearing phase (determination of support needs)	2 to 4 initial home visits					
Number of follow-up visits	8 Follow-up home visits	16 Follow-up home visits	4 Follow-up home visits	Follow-up home visits	6 Follow-up home visits	6 Follow-up home visits

* BABELUGA = Berliner - Obesity therapy programme for children, adolescents and their families - Exercise, counselling, support - Eating and drinking, personal initiative - Learning, quality of life - Family support - Group therapy for children and parents - Obesity diagnosis, long-term weight loss
† P = Percentile

of four support modules, which differ in the number and content of the home visits (see table 3).

During the home visits, the coaches help the parents to identify suitable activities and offers in the home environment for a healthier lifestyle. Together with the coaches, the families also set goals for behavioural changes, which are documented by the coaches in the web application and can be accessed by the families.

Evaluation

The evaluation concept is based on a mixed methods approach (effectiveness–implementation hybrid design). It comprises an evaluation of effectiveness (summative evaluation) and an evaluation of implementation (formative evaluation), whereby it is assumed that the quality of implementation influences the results of the intervention or its effectiveness.[17]

Summative evaluation

The summative evaluation of the effectiveness of fruehstArt compared with standard treatment primarily analyses, the change in the main outcome BMI-SDS after 12 months compared with the CG. The change is determined using the BMI $=\frac{\text{body weight in kg}}{\text{height in } m^2}$ and taking into account the Box-Cox power transformation (L), median (M) and coefficients of variation (S), which describe the gender-specific distribution of BMI by age ($BMI-SDS=\frac{\left(\left(\frac{BMI}{M}\right)^{L}-1\right)}{(L*S)}$).[18] These calculations are based on the BMI distribution of a German reference population of children (see Kromeyer-Hauschild *et al*[19]). The BMI-SDS enables an assessment of individual changes in a child's BMI over time, considering age-specific changes and gender differences in BMI.

Analogous to the main endpoint, changes after 12 months (T2) compared with the initial value (T0) are considered for all secondary target variables (results from questionnaires, motoric test, etc.). The evaluation is carried out according to a modified intention-to-treat (ITT) principle.[20] This means that all eligible and randomised patients, for whom valid BMI-SDS values at time T0 and at least one follow-up value were documented, will be evaluated. An ITT analysis for all randomised children with multiple imputation of missing values as well as protocol-based analyses (per-protocol principle, PP) is carried out secondarily (see online supplemental file 1, SAP). Due to the differences in the prevalence of overweight in children described in the literature, subgroups based on language, gender and socio-economic status (SES) of the child are also considered, if sample size is sufficient. Data will be analysed by linear mixed-effects models for repeated measurements.[21] The model includes the fixed effects treatment group, time, BMI-SDS at baseline (T0), language and gender of the child, as well as an interaction between treatment group*time and a random effect (random intercept) for the coaches. The influence of missing data will be analysed in sensitivity analyses using controlled imputation via pattern-mixture models (see online supplemental file 1, SAP). The entire data analysis is carried out with statistical software environment R.[22] A full description of the planned analysis is found in the SAP (see online supplemental file 1).

Formative evaluation at process level

The formative evaluation at process level examines the implementation process over the entire study period and is based on the recommendations of the UK Medical Research Council for process evaluation.[23] In order to assess the quality of implementation, both quantitative data (implementation index) and qualitative data (interviews) are employed. The evaluation of the qualitative data is carried out according to the qualitative content analysis (see Kuckartz[24]) and will be conducted with the MAXQDA software (V.2020).

To determine the quality of implementation, a quantifiable index based on the work of Dowling and Barry[25] is created for each family participating in the intervention. The Index comprises multiple components, each capturing distinct aspects of implementation: dose, adherence, quality of implementation and responsiveness. A categorisation into 'very low implementation', 'low implementation', 'high implementation' and 'very high implementation' is intended to help determine whether higher implementation is associated with a better intervention effect on primary and secondary outcomes. The required data are recorded via the coaches' and parents' entries in the web application at time points T1 and T2.

In addition to the implementation index, individual semistructured interviews are carried out with families, coaches and paediatricians to more precisely identify enabling factors and barriers to implementation and thus project success. All interviews will be conducted by a member of the study team from the University of Potsdam, Faculty of Human Science, Department Sports and Health Sciences (former Department of Health Sciences, Fulda University of Applied Sciences). Recruitment for the individual interviews of the parents of the participating children takes place continuously. When theoretical saturation is reached, recruitment ends.[26] The aim is to represent the parents as comprehensively as possible based on the criteria (1) BMI-SDS of the child, (2) age of the child, (3) gender of the child, (4) migration background of the parents, (5) subjective social status of the child's parents and (6) time of recruitment. The interviews with the families, coaches and paediatricians are semistructured and based on a predeveloped interview guide.

Formative evaluation at system level

The formative evaluation at the system level aims to identify barriers and facilitators, including regional factors, that impact the integration of the new care model, fruehstArt, into standard practice. Paediatricians in the outpatient sector play a central role in the new form of care, and for successful implementation, it is necessary to know the attitudes of service providers and to identify mechanisms

that promote the willingness to adopt the new form of care in the long term. The formative evaluation at the system level comprises a nationwide cross-sectional questionnaire survey among outpatient paediatricians and subsequent qualitative focus groups. In order to meet the focus on the exploratory analysis of care provision and to obtain as specific, practice-oriented insights as possible, the survey will mainly consist of items specifically conceptualised for this survey. It covers the paediatricians' assessment of the prevalence and relevance of overweight and obesity in their own practice, the current provision of care, an evaluation of outreach counselling by coaches, digital support services and paediatric rehabilitation as well as a final appraisal of the new form of care fruehstArt. In addition, sociodemographic information on the respondent and supplementary information on the corresponding paediatric practice was collected. The results of the standardised survey will be discussed and concretised in the focus groups, for example, with regard to regional particularities.

Health economic analysis

Obesity in early childhood (ICD-10-GM E66.04) predisposes to later chronic diseases such as diabetes or coronary heart disease, which are associated with significant healthcare costs.[27] As part of a health economic analysis, the prevention measures implemented in the fruehstArt project are to be evaluated to show the monetary effects of avoiding secondary diseases over a medium to long-term period. Therefore, decision-analytical modelling from the perspective of the health insurance funds will be used for the health economic analysis. The costs and effects of the alternatives to be compared (fruehstArt vs routine care) will be mapped over a long-term time horizon, thus extending the 12-month study period. The extrapolation will be based on a literature review and the involvement of clinical experts. The analysis will consider treatment guidelines for both prevention and treatment therapy of obesity in children and adolescents with regard to secondary diseases and life expectancy. Different assumptions are made for the maintenance of weight reduction after the end of the study (i.e. recurring weight gains are also adequately considered via sensitivity analyses). The possible occurrence of a metabolic syndrome with type 2 diabetes and cardiovascular diseases as well as musculoskeletal disorders will be modelled as relevant secondary diseases of an excessively high BMI in childhood. The result of the cost-effectiveness analysis is presented as costs per year of life gained. The results of the probabilistic sensitivity analyses are presented via cost-effectiveness acceptability curves. The health economic evaluation will be based on SHI routine data of the participants. In addition to diagnoses and sociodemographic data, the routine data also include cost data (costs for outpatient and inpatient care, medicines and medical aids and appliances) during the intervention period. The health insurance funds involved in the project will provide the routine data for the health economic evaluation (including data on diagnoses, utilisation of outpatient and inpatient care services as well as remedies and aids during the intervention period).

Sample size

Summative evaluation

Due to expected nesting effects by the coaches in the IG, a corresponding partial design effect is considered. Based on similar measures reported in the literature with effect sizes of ≥0.4 (slightly conservative), a standardised effect size (delta/sigma) of 0.32 is assumed.[28] With an allocation ratio of 2:1 (intervention vs control), a power β of 0.8, a significance level α of 0.05, an ICC of 0.04[29 30] in the IG, and an average cluster size of approximately 44 (number of children per coach), n=568 analysable children are required (n=396 participants for the IG and n=172 participants for the CG) (Stata/SE 16.1, StataCorp LLC, College Station, Texas; power twomeans 0 0.32, kratio(0.05) m1(1) m2(44) rho(0.04)). Assuming a drop-out rate of 30% of all participants included at the beginning of the study, the actual number of cases required is approximately n=812 participants (812 (participants included at the beginning)*0.7=568 (participants after drop-out), n=541 participants for the IG and n=271 participants for the CG).

Potential analysis (available SHI data for the economic analysis)

The participating SHI funds (AOK Rheinland/Hamburg, BARMER, TK, IKK classic, HEK) together cover approximately 70% of the market share of SHI-insured persons in the North Rhine region. The overall prevalence of children with overweight (>90th percentile including obesity) in the age group 3–6 years is 10.8% for girls and 7.3% for boys according to KiGGS wave 2 (2014–2017).[1] Girls and boys with low SES have a higher prevalence of obesity (girls: 27% with low SES vs 6.5% with high SES). In 2019, there were 373 636 children aged 3–6 years in the catchment area of the participating obesity centres, according to the North-Rhine Westphalia State Statistical Office (2019). With a 70% market coverage of the participating health insurance funds, this corresponds to approximately 261 545 children. According to the KiGGS study mentioned above, 13 704 girls and 9830 boys are overweight or obese. This results in a total estimate of approximately 23 534 children with overweight/obesity. Stratified across both genders, this results in an overall prevalence of 9%. With a recruitment target of 812 children in 2 years (including a drop-out rate of 30%), 4.49% of children with overweight/obesity in the catchment area of the obesity centres must, therefore, be recruited.

Formative evaluation at process level

For the individual interviews, a target of at least 15 to 20 parents and approximately 10 paediatricians and 14 coaches representing a complete census of the target population is aimed for and considered appropriate for the present research question.

Formative evaluation at system level

For the cross-sectional survey, the target number of cases was between 562 and 750 paediatricians. Based on an expected response rate of 15%–20%, a random sample of 3750 paediatricians was invited to participate. The sample was drawn of all paediatricians registered in the German Federal Physician Register, that is, of all paediatricians providing SHI-accredited outpatient care.

The number of workshops and participants is based on the heterogeneity of the population and the complexity of the topic. A number of five workshops, each with 5–8 paediatricians, is considered appropriate in order to adequately capture regional characteristics (e.g. rural vs urban, northern vs southern, new vs old federal states, consideration of social hotspots) and to develop specific recommendations for the transfer of fruehstArt into standard care.

Ethics and dissemination

The study was reviewed and has received ethics approval in a coordinated procedure from the ethics committee of the Medical Faculty University hospital of Cologne (coordinating ethics committee, reference number: 23–1216) and the ethics committee of the North Rhine Medical Association and has been registered within the German Clinical Trial register (DRKS00030749). All families receive a written declaration of consent together with the study information, in which the families give their written consent to the storage, processing and linking of all data collected. This also includes the planned data linkage of the study data with the SHI service data. All personal data (contact details) will be removed for the data analysis in order to ensure pseudonymisation, particularly with regard to data linkage. All survey data (written surveys, interviews, focus groups) are processed in accordance with the provisions of the European General Data Protection Regulation and its implementation in the German Federal Data Protection Act (BDSG). An example of the participant consent form is attached as online supplemental file 4.

The fruehstArt consortium has agreed on publication guidelines and a publication strategy. The publication strategy consists of the dissemination in scientific peer-reviewed journals and presentations at national and international academic conferences. Professional exchange and the involvement of affected families will be an important part of the project in order to establish a successful new form of care and achieve sustainable research results. To this end, a website and social media accounts have been set up to disseminate up-to-date information about the project.

DISCUSSION

fruehstArt aims to fill a gap in the German healthcare system by offering early intervention for overweight and obesity in children between the ages of 3 and 6. It uniquely combines home-based counselling, an e-health platform and existing SHI financed offers and offers from cities/municipalities and specifically targets German and Turkish-speaking families to promote healthier lifestyles and prevent obesity in adulthood.

Not only in Germany, but also in an international context, overweight and obesity in children is a widespread issue and a significant global health problem. The international scientific community has made significant strides in understanding and addressing childhood obesity and numerous international research studies and projects are dedicated to the prevention of this disease.[31–33] The WHO advocates comprehensive, population-based strategies that include the promotion of healthy eating and physical activity and the creation of an enabling environment. These strategies are essential to tackle the multifaceted problem of obesity.[34] In this context, fruehstArt's approach seems particularly innovative. By focusing on early intervention,[35 36] fruehstArt starts at a critical stage of child development, which is crucial for establishing healthy habits that can prevent obesity later in life. The integration of home-based counselling, an e-health platform and existing SHI-funded services as well as municipal services offers a holistic support system. In addition, fruehstArt's focus on German-speaking and Turkish-speaking families emphasises the importance of cultural sensitivity and inclusivity in health interventions. Studies have shown that culturally appropriate programmes are more successful in engaging participants and achieving the desired health outcomes.[37] By addressing specific linguistic and cultural needs, fruehstArt improves its accessibility and effectiveness, promotes healthier lifestyles and prevents obesity in adulthood.

Strengths of fruehstArt

Innovative components in fruehstArt are (1) the assessment and outreach counselling by a trained coach in the home environment, (2) the use of an app to promote the jointly agreed, individually formulated goals, (3) the coordination and integration of services provided by SHI, the DRV and their linking with other services offered by cities/municipalities and other providers. The latter strengthens cross-sectoral cooperation and enables affected children to access rehabilitation services at an early stage.

fruehstArt is expected to make an important contribution to improving the care of children with overweight and obesity, in particular through:

- the cross-sectoral linking of services offered by SHI, DRV and other providers.
- The creation of a care programme for children between 3 and 6 years of age for whom there are neither regular SHI benefits nor rehabilitation offers for early overweight reduction and obesity prevention.
- Supporting paediatricians in their task of prevention.
- Improved access to existing services and support offerings.
- Linguistic and cultural adaptation to improve use and impact among Turkish families.

Challenges and limitations

The main challenge is to recruit the required number of (1) paediatricians, (2) children with overweight/obesity and their parents and (3) Turkish-speaking children with overweight/obesity.

The following measures to minimise these risks are implemented in fruehstArt:

- Consideration of an appropriate drop-out rate for the estimation of the number of subjects/children to be recruited in order to achieve the required sample size.
- Motivating paediatricians and families to participate in the CG: parents in the CG receive the same motivational lifestyle advice by the treating paediatrician as the IG when they register and an adapted version of the app for answering the evaluation questionnaires.
- Field access for the recruitment of Turkish-speaking families through the 'neighbourhood mothers'.
- Paediatricians are recruited via the KV Nordrhein, the BVKJ regional association, the networks of obesity centres, via further training events and through cold calling by trained study coordinators.

Another challenge, due to the nature of the behavioural intervention, is that blinding of participants and care providers is not feasible. While the primary endpoint (BMI-SDS) is based on objective measurements taken in paediatric practices, the secondary motor skill test is administered by unblinded personnel (coaches for the IG and study coordinators for the CG), which introduces a potential risk of assessment bias. To minimise this bias, the motor skills test is conducted in a highly standardised manner (as with the U examinations carried out by a paediatrician). Additionally, several secondary endpoints (e.g. nutrition, media consumption, parental quality of life) rely on parental self-reports via questionnaires, which are susceptible to recall and social desirability bias. For these domains, however, parental report represents the only feasible source of information, and we sought to minimise bias by employing validated instruments, standardised administration procedures and ensuring equal conditions across both study arms. Regarding the study design, there is a possibility of contamination or attenuation of the observed effect size, as the CG also receives motivational interviewing from their paediatrician within the study protocol. However, such motivational conversations are not entirely novel, since most paediatricians already incorporate similar discussions into routine care. Therefore, while some overlap between study arms cannot be excluded, we anticipate that the resulting risk of contamination will be small. We also acknowledge the risk of attrition common to longitudinal lifestyle interventions, which we have accounted for in our sample size calculation by assuming a dropout rate of up to 20–30%.

Furthermore, the generalisability of our findings may be limited by the regional focus (North Rhine, Germany) and the restriction to families with sufficient German or Turkish language skills. At the same time, the project incorporates a system-level evaluation conducted nationwide, which explores potential barriers and facilitators of implementation from the perspective of paediatricians. This broader assessment provides insights into whether obstacles are region-specific or reflect challenges that are consistent across Germany, thereby informing the transferability of the intervention beyond the study region.

Finally, as fruehstArt is a complex, multicomponent intervention, we cannot disentangle the specific contribution of individual elements (e.g. the app vs the home visits). Consequently, the estimated treatment effect pertains to the integrated care package as a whole—comprising coaching, digital support and facilitated access to cross-sectoral services including rehabilitation—rather than the coaching component alone. Nevertheless, we assume that the coaching element, which is layered on top of the other components, exerts a particularly strong influence on families' everyday habits and may be a key driver of change within the overall package.

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