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Study protocol for a feasibility study of microinterventions in smartphone-based assessments to reduce depressive rumination

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ABSTRACT

Introduction Depression as well as suicidal ideation and behaviours share several precipitating and maintaining factors and are subject to the influence of overlapping constructs. One of these transdiagnostic constructs is rumination. For the treatment of rumination, a variety of interventions are already available. However, not everyone with a need receives psychotherapeutic treatment. And even if they do: implementing learnt strategies alone at home can be challenging for patients. Therefore, this study aims to test the feasibility of delivering microinterventions for the reduction of rumination in a smartphone-based setting with the goal to make these interventions accessible to a larger number of people and support their use in everyday life.

Methods and analysis The study's design is an uncontrolled-within-group design. Participants with at least mild depressive symptoms and reported rumination will be included and recruited via outpatient clinics as well as in the general population. The aim is to recruit at least N=70 participants. Participants first undergo a short telephone screening, a baseline assessment, a 7-day smartphone-based assessment including microinterventions in case participants report rumination and a postassessment. For feasibility purposes, primary outcomes relate to participants' compliance, their evaluation of the smartphone-based assessment as well as the microinterventions delivered during the assessment. As a secondary goal, clinical utility will be examined. Clinical outcomes (eg, depressive symptoms, rumination) will be measured at baseline and postassessment.

Ethics and dissemination The ethics committee of the institute of psychology of the university of Duisburg-Essen and University of Leipzig has approved the study. Study results will be disseminated to healthcare communities, in peer-reviewed science journals and at conferences.

Trial registration number DRKS00031743.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The main limitation of this study is the missing of a control group.
⇒ The main strength of this study is the implementation of microinterventions within the smartphone-based assessment.
⇒ Another strength of the study is that the interventions will be delivered just in time depending on the participants' needs.

INTRODUCTION

With 264 million people affected, depression is one of the most common mental illnesses worldwide.[1] In addition to a wide range of symptoms, people with depressive disorders also have a significantly increased risk of suicidal ideation and behaviours compared with the general population.[2] However, suicidal ideation and behaviours are not only symptoms of depressive disorders; but also share several precipitating and maintaining factors and are subject to the influence of overlapping mechanisms. Internal and external entrapment (the feeling of being trapped with no way to escape) has been widely studied in relation to depression and suicidal ideation.[3] However, more recent research has emphasised the importance of internal entrapment, which can result from so-called rumination.[4] In a study of N=308 participants who had been admitted to a psychiatric ward due to an acute suicidal crisis or suicide attempt, only internal entrapment was able to predict suicidal ideation within the timeframe of a year.[4] Rasmussen *et al*[5] also found internal entrapment to be more relevant in the development of suicidal ideation. They stated that it might be more complicated for affected persons to escape reoccurring and aversive internal cognitive states such as rumination than to escape external circumstances.

One model explaining the development of suicidal ideation and the transformation from suicidal ideation to suicidal behaviour is the Integrative Motivational-Volitional Model of Suicidal behaviour model from O'Connor and Kirtley.[6] In this model, rumination is highlighted as a moderating factor influencing feelings of entrapment and thereby

the development of suicidal ideation. So far, research has shown that rumination leads to internal entrapment[5 7] and internal entrapment leads to depression[8] as well as to suicidal ideation.[4] Rumination, as a form of perseverative thinking, has already been understood to transcend depression and suicidal ideation as a transdiagnostic cognitive mechanism and therefore also promotes the development and maintenance of other mental disorders making it a crucial factor in the development of psychopathology.[9]

Although empirical studies have demonstrated the efficacy of cognitive behavioural therapy (CBT) interventions in reducing rumination,[10] there are two issues that limit the extent of potential effects:

1. In outpatient psychotherapy practice, 74% of people with major depression do not receive guideline-based treatment,[11] and even if they do, patients are left to their own devices between regular sessions. The method of 'homework' in behavioural therapy can help to continue working on the treatment goal between sessions, but requires a high level of drive, self-motivation and willingness of the patients,[12] which are not always present due to depressive symptomatology.[13] Furthermore, it is helpful to use an intervention exactly when it is needed. Thus, rumination processes can be resolved outside of the therapy setting.
2. It could be established for depressive symptoms[14] as well as for entrapment[15] and suicidal thoughts[16] that their expression already changes over short periods of time. Patients may be overwhelmed by these rapid symptom increases or decreases. Additionally, it has been shown that rumination is expressed in certain situations and is triggered by different triggers depending on the person.[17]

Ecological momentary assessment (EMA), that is, repeated questioning by means of a smartphone, offers a solution for recording these fluctuations. EMA offers a very good opportunity to assess people repeatedly within short periods of time in their familiar environment without much additional effort for the persons concerned.[18] Both the long-term course of depression and reactive processes can be measured more precisely with this method than with the conventional retrospective self-report (questionnaires) in clinical practice.[19] Additionally, this form of assessment captures changes in symptoms from one measurement to the next and thereby offers the possibility to implement interventions in the needed moment. Therefore, this research project aims to investigate EMA-based microinterventions for the reduction of rumination that are easily accessible for participants within the framework of a feasibility study. The special feature of this study is that the participants are continuously questioned about their affective states and the interventions are only offered when needed (ie, in the case of pronounced momentary rumination). The main research goals of this feasibility study are twofold: (1) the examination of participants' compliance during the EMA phase and (2) the evaluation of the study (assessment and interventions) through study participants. Additionally, we are interested in the following secondary research questions (3) the clinical utility of this assessment by examining (3a) the subjective opinion of licensed clinical psychotherapists for CBT, (3b) participants' use of the intervention and (3c) the preliminary effectiveness of the interventions (because there is no control group at this stage and the main goal is to test the feasibility).

The specific hypotheses regarding the main research questions on compliance are the following:

(1a) Higher rumination and depressiveness in the presurvey are related to a higher compliance in the EMA phase.

(1b) There is no correlation between age and compliance of subjects in the EMA phase.

(1c) There are gender differences regarding the compliance in the EMA phase. Women will have a higher compliance than men.

(1d) Participants who are employed will show a lower compliance than unemployed participants.

METHODS AND ANALYSIS

The whole protocol (V.1, 09 May 2023) is reported according to guidelines presented in the Consolidated Standards of Reporting Trials 2010 statement extension for pilot and feasibility studies.[20]

Patient and public involvement

No patients were involved in the study design. Two psychotherapists will evaluate the utility of study from a psychotherapeutic view with the help of a semistructured interview.

Design

The design of the study is an uncontrolled, within-group, baseline-assessment, 7-day EMA phase, postassessment design. All participants receive the microinterventions delivered during the EMA phase.

Eligibility criteria

Participants will be included in the study when they are of full age (at least 18 years or older), they report at least symptoms of a mild depressive episode as well as rumination. Therefore, a research assistant will conduct the Beck's Depression Inventory (BDI) on the phone with the respective participant. If the participant reaches a score ≥9, a mild depressive episode can be diagnosed according to validated cut-pff criteria[21] and the participant fulfils this criterion. Additionally, participants will be asked whether they ruminate with a yes or no question. Participants will be excluded in case of inpatient treatment, outpatient psychotherapy (max. consultation hours+probation), day clinic and/or lack of language skills. Eligibility criteria will be screened in a short telephone interview.

Sample size

Given our experiences with EMA studies and participants' compliance, we conducted power analyses for the EMA

setting first. A sample of N=70 participants is needed to detect medium effects given our sampling schema and a compliance of 75%.[22] All further power calculations were conducted with G*Power.[23]

For the first main research goal regarding participants compliance, correlation analyses, as well as t-tests, will be conducted. For correlation analyses, with a sample of N=70 participants, a power (1–ß) of 0.82 can be reached. For the one-tailed t-tests, N=70 participants a power (1–ß) of 0.67 can be reached. For the second main research goal regarding the study evaluation, only descriptive statistics will be used.

For the secondary questions regarding the third research goal, a sample of N=54 (1–ß=0.95, f=0.25) is needed to detect the main effects of the effectiveness of the interventions in the pre–post comparison on rumination, entrapment as well as the depressive symptomatology of the test persons with medium effect size.

Therefore, we aim for a sample of at least N=70 participants.

Recruitment

Data collection will take place from June 2023 to June 2024 at the latest. If the targeted sample size N=70 is reached before the end date, data collection will be continued until the end of the funding. Please note that data collection started while the study protocol was initially reviewed by *BMJ Ope*n. The procedures, methods and design remained unchanged during the revision of the protocol.

The study participants will be recruited via social media (including Facebook and Instagram) as well as via flyers displayed at the University of Duisburg-Essen and the associated university outpatient clinic and cooperating outpatient practices as well as cooperating outpatient practices in Leipzig. Flyers include information on the type of study, that there will be exercises for reducing rumination, and that there will be no incentive (except the possibility of study credits for students). Inclusion criteria are ensured in a brief telephone interview.

Reasons for non-participation

Possible reasons for non-participation could be that participants do not meet the inclusion criteria that they feel to burdened to participate or because they think that participation involves more effort than benefit. There is also the risk for high drop-out rates because participants must pass through multiple assessments. A flow chart for drop-out will be updated regularly during data collection.

Data collection

Telephone screening

Participants will be provided with a study email address. Those who will contact the research team will undergo a short telephone screening. Participants will be given information on the procedure of the study (see informed consent in online supplemental material). Additionally, the BDI[21] will be conducted to ensure that only participants with at least mild depressive symptoms will be included using a validated cut-off criteria (sum score ≥9[24]). Participants will be also asked whether they ruminate (screening question: yes/no) and whether they receive any kind of psychotherapeutic treatment currently (exclusion criteria). Participants will be asked to use their own cell phone (participants will be provided with a study cell phone in case they use Apple products because those are not supported by the used software). A lab appointment will then be arranged.

Baseline assessment and informed consent

Participants will come to the lab for a face-to-face meeting. First, patients will give consent to participate in the study. The participant consent form can be found in online supplemental material. A baseline assessment consisting of eight questionnaires will be conducted using the online tool www.soscisurvey.de. The questionnaires include measures on rumination, metacognition, entrapment, depressive symptoms, emotion regulation and suicidal ideation and behaviours (for an overview see table 1). After the assessment, participants will be introduced to the procedure during the EMA phase. The available microinterventions will be explained and shortly demonstrated.

The EMA phase will be conducted with the App movisensXS running on Android smartphones only. MovisensXS meets all requirements of the European General Data Protection Regulation. Participants, who do not have an Android smartphone but want to participate, will receive a study smartphone from the respective study site. As we have done this in previous studies, this does not

Table 1 Overview of the questionnaires used in the baseline and postassessment

Perseverative Thinking Questionnaire	PTQ	Ehring *et al*[31]
Metacognitive Questionnaire-Short Version	MKF-30	Arndt et al[32]
Shortversion of the Beck's Hopelessness Scale	BHS-9	Forkmann *et al*[33]
Entrapment Scale	ES	Trachsel *et al*[34]
Beck's Depression Inventory	BDI	Beck *et al*[21]
Emotion-Regulation Questionnaire	ERQ	Abler and Kessler[35]
White Bear Suppression Inventory	WBSI	Wegner and Zanakos[36]
Scale for Suicidal Experience and Behaviour	SSEV	Teismann *et al*[37]

affect on feasibility outcomes. The typical phone use of participants in general will not be assessed.

EMA phase

One day after the laboratory appointment, the 7-day EMA phase begins.

Every morning, there will be a short morning assessment on sleep quality and rumination during the night. Then a mindfulness intervention follows. During the assessment days, patients receive randomised prompts five times between 8:00 and 20:00 hours. Each of these assessments includes 25 momentary items for rumination, depressive symptoms, hopelessness, metacognition, positive and negative affect, and suicidal ideation via smartphone. In case they report rumination during these assessments (rumination>0), they get to choose one of three microinterventions, which will be explained in the following paragraph. Additionally, there is one last assessment every night (22:00 hours). During the 7-day EMA phase, patients can also contact the study team in case of any technical problems or questions.

Interventions

All interventions are based on the Manual for Cognitive Behavioural Therapy of Depressive Rumination by Teismann *et al*,[25] which includes three domains:

- Distraction: Even a brief period of distraction can help to brighten a person's mood in the short term; furthermore, distraction counteracts the intensification of negative cognitions, motivational difficulties and problem-solving deficits.[26]
- Activity: Physical activity is particularly mood-brightening in the context of depression and rumination.[27]
- Mindful distancing: The aim is to change one's attitude toward one's own thoughts and not to deal with them actively or analytically, but to encounter them metacognitively.[28]

The morning exercise

Every morning, a professionally recorded mindfulness exercise on detached mindfulness will be presented to participants (length 2:31 min). The exercise is called 'floating leaves in the river' and belongs to the module of mindful distancing in the manual. The exercise is important to practice because the microintervention on mindful distancing refers to this exercise.

The three microinterventions (explained below) are exercises (1–3 min) including all three domains mentioned above.

Distraction

For this study, a cognitive form of distraction was chosen. The participants will be asked to form word chains. The last letter of the first word forms the new word that follows it. The participants will be asked to form a word chain containing at least 10 consecutive words to ensure sufficient distraction and to challenge the participants cognitively.

Becoming active

Participants will be asked to perform 10 squats and 5 jumping jacks. If the current situation does not allow it, because they are at work or otherwise prevented, they are given the task of becoming active otherwise (eg, go to the toilet and back, walk stairs).

Mindful distancing

In the small exercise 'mindful distancing', the participants will be asked to recall the morning exercise and to let their thoughts 'float away on the river'.

Postassessment

After the EMA phase, participants will be asked to fill out one last online survey including all questionnaires from the baseline assessment as well as an evaluation questionnaire with questions regarding both the EMA phase in general (eg, technical problems, feasibility in everyday life, special life events during the assessment period) and the interventions during the EMA phase (eg, subjective utility of the interventions, most favourable intervention).

For the whole data collection procedure, see figure 1.

OUTCOME MEASURES AND ANALYSES

Examination of participants' compliance during the EMA phase

A variable with compliance in percentage as an outcome measure will be computed including the number of completed assessments during the EMA phase. Means and SDs of this variable will be reported.

Additionally, with regard to the hypotheses 1a–1d, correlation analyses will be conducted to see whether compliance is positively correlated with rumination and depressiveness as well as age in the baseline assessment. Two independent t-tests will be conducted to see whether there will be gender differences or differences with regard to occupation (employed participants vs unemployed participants).

Evaluation of the study (assessment and interventions) through study participants

A short questionnaire with questions regarding the evaluation of the study was developed using Likert scales as well as free response fields. The evaluation questionnaire includes 16 items concerning the length of interventions, the subjective effectiveness of the interventions, how much participants liked the interventions, the use of interventions, the necessity of the interventions, the engagement in the interventions and the subjective gain through the interventions.

The second evaluation questionnaire includes 26 items concerning adverse events during data collection, (subjective) negative effects through data collection, any kind of technical problems, pre-experiences with such interventions and questions about the usability of the study (eg, number of alarms, length of interventions and clarity of instructions).

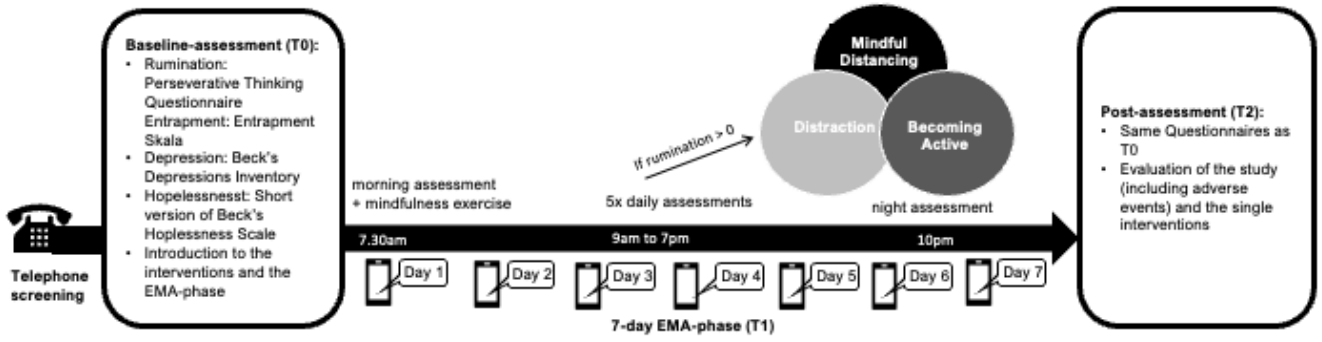

Figure 1 Study procedure including for the baseline- and post-assessment as well as the EMA (Ecological Momentary Assessment) phase.

The questions either ranged from a Likert scale from 1 to 5 or included dichotomous items (eg, yes/no). For some questions, there was also the possibility to enter a free text.

Frequencies, means and SDs of all variables will be reported and visualised.

In terms of the evaluation of the study, a clinical advisory board with n=3 members has been established. They are informed on the procedure of the study and will be regularly updated. All reported adverse events and negative effects will be discussed.

Clinical utility of the study

Subjective opinion of licensed clinical psychotherapists for CBT

A short interview will be conducted during recruitment time with n=2 licensed clinical psychotherapists for CBT who do not work as researchers but as therapists only. Two therapists who agreed to distribute flyers of the study will be asked to evaluate the study. They will be introduced to the study design and will be asked questions concerning their subjective evaluation of the study design for patients as well as for the interventions using Likert scales as well as free response fields. Means and SDs of all variables will be reported. In combination with the subjective experiences from the participants during the postassessment, we expect to gain a multifaceted view of the microinterventions integrating different perspectives.

'Effectiveness' of the interventions

To examine effectiveness, all used questionnaires will be compared (pre–post) using paired t-tests. The dependent variable will be the respective construct (eg, depression, rumination) and the independent variable will be the measuring time. Additionally, a regression analysis will be calculated including rumination, depressive symptoms and entrapment at the baseline assessment as predictors and rumination at postassessment as the outcome variable.

Please see table 1 for an overview of the questionnaires at baseline and postassessment.

ETHICS AND DISSEMINATION

The study has been approved by the Ethics Committee of the University of Duisburg-Essen (no approval number) and the Ethics Committee of the University of Leipzig (199/23-Ik) and will be conducted in accordance with the Declaration of Helsinki[29] ensuring the rights of all participants. Confidentiality will additionally be guaranteed because all project members have filled out and signed confidentiality agreements concerning all study information. Before starting the assessment, all participants will be informed about the purpose of the study, the voluntary nature of participation, data storage and security, and give informed consent prior to participating. Additionally, addresses for helplines and contact information for therapy institutions will be provided. All participants will be provided with a study code to deidentify their data but to still be able to match baseline assessment data with EMA and postassessment data. Personal information of participants will be stored separately from the deidentified data. This personal data will be stored in a locked safe accessible only to the research team.

Furthermore, any adverse events or negative effects of the study will be collected during the postassessment. These events and effects will be reported when publishing findings of this study. Additionally, they will be reviewed with the clinical advisory board. Study

findings will be published in open-access journals and will be presented at both national and international conferences.

DISCUSSION

Rumination is a transdiagnostic symptom of both depression and suicidal ideation and behaviours and there are multiple ways to treat it.[10] However, not all patients in need receive the psychotherapeutic treatment they need.[11] Reasons for this may include treatment that is not in accordance with guidelines,[11] lack of patient drive[13] or rapid changes in symptoms over time[14] and the associated varying need for treatment.

Given these problems, both a frequent recording of symptoms, considering their temporal dynamics and treatment methods that are offered when the patient needs them are necessary. Smartphone-based surveys (EMA) offer the possibility to ask patients about their symptoms in a close-knit and familiar environment.[30] The possibility of using EMA to record the extent of central symptoms and constructs such as rumination in a relatively high-frequency and ecologically valid way in the patient's everyday life now opens up new, as yet underused possibilities for improving psychotherapeutic support for patients with depression and suicidal ideation and behaviours and might be specifically aid in transferring interventions to everyday life.

Most importantly, this study presented in this protocol will examine the feasibility and the possibility of the clinical utility of this study using smartphone-based assessment methods in combination with microinterventions. The main research goals of this feasibility study are twofold: (1) the examination of participants' compliance during the EMA phase and (2) the evaluation of the study (assessment and interventions) through study participants. Additionally, we are interested in (3) the clinical utility of this assessment by examining (3a) the subjective opinion of licensed clinical psychotherapists for CBT, (3b) participants' use of the intervention and (3c) the effectiveness of the intervention (but careful: there will be no control group at this stage).

The main goal is not to test efficacy of the interventions but to evaluate whether this kind of study is feasible for burdened participants. The results of this study should, therefore, be the groundwork for a future (maybe improved) study including a control group. Of course, all study results regarding the side question (3c) are very limited without a control group.

Given the novelty of this specific study design and the missing studies on the feasibility and acceptability of such a design, we hope to gain important information from conducting this study and use the study results for the development of a randomised clinical controlled trial study to implement the interventions within the psychotherapeutic outpatient context in Germany.

STUDY STATUS

Recruitment started in June 2023.

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Contributors The research idea originally came from IH. IH and LS conceptualised the study. IH wrote the manuscript. LS supervised the process. Both authors read and approved the final version of this manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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Information on study participation and informed consent

(the original version is in German, we only translated the consent form for publishing purpose)

Welcome to our study! Thank you very much for your interest and your willingness to support our study with your cooperation.
In order to participate in the study, we would like to ask you to read the following information carefully. It will inform you about your rights as a participant and our obligations as the study management. To participate, you must be at least 18 years old and speak German. As already discussed in the initial telephone contact, you must also have mild depressive symptoms.

1. Background and aims of the study
The aim of this study is to take a closer look at your rumination behavior and the associated feelings of being trapped and hopelessness. In addition, you will be given short exercises.

2. Course of the study

2.1 Overview
- Baseline and one post questionnaire (approx. 10 minutes)
- 7 days smartphone-based survey
    - One fixed exercise once a day at a fixed time in the morning (07:30)
    - 5x daily short surveys and exercises throughout the day
    - Last survey at 9:30 pm

At the beginning and end of the study you will be asked to complete several short questionnaires (the first survey will start after you have agreed to participate in the study). The questionnaires will take about 10 minutes to complete. The questionnaires are self-report questionnaires, which may be stressful for you to complete. In this context, we would like to draw your attention in particular to your right to withdraw from this study (point 3). You can also find help services for mental stress and suicidal tendencies here: *Telefonseelsorge*: 0800-1110111.

Between the two questionnaire surveys, an additional survey will be conducted using a smartphone-based survey. You will receive an explanation of the procedure for the smartphone phase from a member of the study team after completing the questionnaires.

2.2 Procedure for a smartphone-based survey
2.2.1 Morning exercise
The exercise begins daily at 7:30 a.m. with a mindfulness exercise, which will take about 5 minutes. You have the option of postponing the exercise twice by half an hour, after which it is no longer possible to carry out the exercise. After the mindfulness exercise, you will be asked how you felt about the exercise.
Instructions for the mindfulness exercise:
The floating leaves in the river exercise is a mindfulness exercise for which you should consciously take at least 5 minutes every morning. You will receive instructions for this exercise via an audio file. If possible, you should first find a place where you can withdraw for a short time and take a comfortable sitting position.

2.2.2 Daily assessments
In the morning, you will be asked about your sleep for approx. 1-2 minutes. Throughout the day, five additional short questionnaires regarding your current mood will take place between 9 am and 7 pm. These questionnaires will take about 3-4 minutes. Sometimes you are given a short exercise lasting around 30 seconds afterwards.
At 9:30 pm there will be a final survey of your current mood.

3. Voluntary participation and right to withdraw
Participation in the study is voluntary. You can terminate your participation in this study at any time and without giving reasons, without incurring any disadvantages.

4. Right to information and results of the study

You have the right to be informed about the results of the study. Please contact the study management for this purpose.

5. Guarantee of anonymity and data protection
Your data is collected pseudonymously. It is not possible to assign the data to your person except for the study team. The data will be analyzed and used exclusively within the framework of the research project. The collection and processing of personal data is pseudonymized using a respondent code and without providing your name. If the results of the study are published, it is not possible for the data to be attributed to you personally.
No other information is stored that could enable identification, e.g. IP address. The data will not be passed on to third parties unless this is requested when the results are published. Even in this case, it is not possible to link the data to your person. You can withdraw your consent to participate in the research project at any time in accordance with the statutory provisions. Due to the pseudonymized data collection, subsequent deletion of the data is possible on request. All data already collected must be stored for 10 years in accordance with the legal requirements (§ 630f BGB).

If you have agreed to participate in the study, the initial assessment will begin on the following pages, which will take about 10 minutes.
On the following page, you will also be asked to generate your respondent code. You create this code yourself according to the following rule:
1. the third letter of the mother's first name
2. the first two digits of the date of birth (e.g. 04, if birthday on June 04)
3. the third letter of the father's first name
4. the number 3
5. the second letter of the place of birth
We will ask you for this code (including instructions) again for the smartphone-based survey and the final questionnaires so that we can match your answers pseudonymously with your answers from the initial and final questionnaires and the smartphone-based survey. At no time do you have to give your real, full name, so that your code cannot be linked to you personally at any time. As the instructions for creating the code are always the same, you do not need to write it down or memorize it.
If you have any further questions, please contact the study management.

Declaration of consent
I have read and understood the participation information for the study in full and agree to participate in the study.