Study protocol

1. Title

Randomized-controlled pilot trial to test the effectiveness of an internet-based intervention to promote mindfulness in college students
("StudiCare Mindfulness")

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2. Responsibilities

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3. Summary

Background: Study-related stress and psychological problems are common among college students, but few affected individuals seek professional help. The effectiveness of mindfulness interventions in reducing symptoms of stress, depression, and anxiety has been demonstrated many times in both clinical and healthy samples. Mindfulness can be successfully learned using Internet-based interventions (IMIs), a promising new prevention and treatment approach with the potential to target students who cannot be reached by other means. Therefore, this randomized controlled trial (RCT) aims to evaluate the efficacy and acceptability of an Internet-based mindfulness intervention specifically developed for college students and guided by e-coaches on a nationwide, cross-curricular sample in Germany, and to explore potential moderators and mediators.

Methods: In this two-arm RCT, the guided IMI "StudiCare Mindfulness" is compared with a wait-list control group (WL). Inclusion criterion is a score of ≤ 37 on the short form of the Freiburg Mindfulness Inventory (FMI). "StudiCare Mindfulness" consists of 5 modules with different topics on mindfulness, based on acceptance and commitment therapy (ACT). The recruitment via internet as well as on-site at different universities will take place in the period from May to September 2017 in German-speaking countries (Germany, Austria, Switzerland) and uses the established recruitment strategy of the StudiCare project. This enables the achievement of the calculated sample size of N=150. Assessment will take place before as well as six weeks after randomization. The WL will receive the unguided version of "StudiCare Mindfulness" at the completion of the post-measurement time point. The primary outcome is mindfulness as measured by the FFA. Secondary outcomes will be depression, anxiety, and stress symptoms, quality of life, and intervention satisfaction, adherence, and acceptance. Potential influencing variables will include demographic variables.

Discussion: The results will expand the evidence base for the effectiveness of Internet-based mindfulness interventions for an international cross-disciplinary student sample and contribute important information regarding the acceptability and adherence of Internet-based interventions among students. Insights into potential moderators and mediators may also provide information for optimizing interventions and selecting optimal target groups.

Keywords: mindfulness, randomized-controlled trial, stress, depression, anxiety, Internet- and mobile-based intervention

4. Scientific background

Stress and psychological problems are common among students: In a large-scale WHO survey of students from 21 countries, more than 20 percent of students met a 12-month diagnosis for a mental disorder. A quarter of those reported receiving some form of treatment (Auerbach et al., 2016). These findings are consistent with a German study by Bailer, Schwarz, Witthöft, Stübinger, and Rist (2008). Here, the PHQ-D criteria (patient health questionnaire) for at least one mental disorder (excluding alcohol syndrome) were found to be met by nearly 23 percent of students at the University of Mannheim. According to a study by the University of Heidelberg, symptoms such as depressiveness, anxiety and psychosomatic complaints often mask work disorders, test anxiety and interpersonal difficulties (conflicts with parents, partners, contact problems); increased stress also contributes to mental illness (Holm-Hadulla, Hofmann, Sperth, & Funke, 2009). The perceived stress level among German students is also significantly higher than in the general population. For example, almost a quarter of the students questioned in a survey by Techniker Krankenkasse (2015) on student health in Germany reported being frequently stressed.

Among other things, mindfulness training has proven to be an effective method for preventing and treating stress and psychological strain. Mindfulness stands for a conscious, judgment-free perception of what is happening in the here and now (Kabat-Zinn, 1994). Closely related to mindfulness, there is also the concept of acceptance. This refers to accepting and allowing one's inner experience, including unpleasant thoughts, feelings, or bodily sensations. Examples of mindfulness-based practices include mindfulness-based stress reduction (MBSR; Kabat-Zinn, 1982, 1990), mindfulness-based cognitive therapy (MBCT; Teasdale, Segal & Williams, 1995; Segal, Williams & Teasdale, 2012), and acceptance and commitment therapy (ACT; Hayes, Strosahl & Wilson, 1999; Eifert, 2011).

Mindfulness can contribute to a better handling of stressful situations and in this way reduce symptoms such as anxiety and depression and prevent the development of mental disorders. The effect of mindfulness-based therapies has been investigated in numerous randomized clinical trials and meta-analyses. For example, in a meta-analysis (39 studies, n = 1140), Hofmann, Sawyer, Witt, and Oh (2010) looked at the effect of mindfulness-based therapy practices (MBSR, MBCT) on anxiety- and mood-related symptoms in clinical samples. Effect size estimation revealed a moderate overall effect in terms of improvement in anxiety symptoms (Hedges' g = 0.63) and depression symptoms (Hedges' g = 0.59). Likewise, in a meta-analysis (19 studies, n = 491), Vøllestad, Nielsen, and Nielsen (2012) examined the effect of mindfulness- and acceptance-based therapies (ACT, MBSR, MBCT, MAGT, MBSM, or

ABBT) on depressive and anxiety symptoms in patients with an anxiety disorder. Compared to the control group, there was Hedges' g of 0.83 with respect to anxiety symptomatology and Hedges' g of 0.72 with respect to depression symptomatology. Other studies specifically address the effect of ACT and were able to show that it is effective in stress prevention and therapy of chronic pain as well as many psychological disorders (e.g., depression, anxiety disorders, post-traumatic stress disorder). Those results are summarized in a meta-analysis of by Hayes et al. (2006; 32 studies, n = 6628).

Internet-based self-help interventions offer a good opportunity to address the high psychological distress of students as well as their rather low seeking of treatment services (Davies, Morriss & Glazebrook, 2014). Their effectiveness is comparable to traditional treatment approaches (Andersson, Cuijpers, Carlbring, Riper & Hedman, 2014; Baumeister, Lin & Ebert, 2017) and they offer numerous beneficial features. For example, the barrier to seeking Internet-based prevention and treatment services may be lower, access to treatment is easier, and waiting times are eliminated. In addition, IMIs can be implemented in a cost-effective manner (Portnoy, Scott-Sheldon, Johnson & Carey, 2008; Christensen & Hickie, 2010).

The effectiveness of Internet-based mindfulness interventions was examined by Spijkerman and Bohlmeijer (2015) in a meta-analysis using 15 randomized clinical trials (n = 2360). It was shown that mindfulness-based online interventions had a small but significant effect regarding improvement in depression symptomatology (g = 0.29), well-being (g = 0.23), and mindfulness (g = 0.32). The largest effect was found for stress reduction (g = 0.51). Significantly higher effects also emerged for guided versus unguided Internet-based interventions with respect to improvements in mindfulness and stress. In another meta-analysis, Jayewardene, Lohrmann, Erbe, and Torabi (2016) considered the effect of preventive Internet-based mindfulness interventions on perceived stress as well as mindfulness. The examined studies were eight randomized controlled trials (RCTs) which included only healthy subjects. The mindfulness-based interventions were mainly based on mindfulness-based stress reduction. After the intervention, there was a significant mean effect regarding perceived stress (g = 0.43) and a small significant effect regarding increases in mindfulness (g = 0.28).

The present planned randomized-controlled trial investigates the effectiveness of a web-based, guided mindfulness intervention for students in a large, representative, cross-curricular sample from the entire German-speaking region (Germany, Austria, Switzerland). The study also considers the conditions under which an intervention works. An analysis of moderators and mediators offers the potential for optimizing interventions and target groups, e.g., by providing

clues on how to adapt interventions to specific needs of certain subgroups. RCTs provide an optimal framework for this (Kraemer et al., 2002). Currently, there is still insufficient evidence on moderators and mediators of Internet-based mindfulness interventions and a need to investigate them in more detail (Spikerman & Bohlmeijer, 2016). For this reason, the proposed study uses an exploratory approach to analyze a range of potential moderators and mediators that have been previously studied in relation to traditional and Internet-based interventions on mindfulness, anxiety, and depression. These include sociodemographic variables and pre-treatment depression (Kuyken et al., 2016), pre-treatment mindfulness (Shapiro et al., 2011), personality traits (De Vibe et al., 2015), and expectations regarding intervention effectiveness (Hedman et al., 2012).

5. Study aims and research questions

5.1 Primary and secondary aims

The aim of this study is to evaluate the effectiveness of the internet-based intervention "StudiCare Mindfulness" for the promotion of mindfulness in students in comparison to a waitlist control group in an RCT. In addition, an exploratory analysis of potential factors influencing the effectiveness of the intervention will be conducted to assess possible differential effectiveness.

Primary outcome is the increase in mindfulness at the post-measurement time point (t2).

Secondary outcomes are reduction in depression, anxiety, and perceived stress, and increase in quality of life. In addition, acceptance will be evaluated in terms of intervention adherence and satisfaction. The collection of formative and summative feedback will also provide information for further optimization of the intervention.

Outcomes will be collected via self-report-based questionnaires prior to randomization (t1) and at post-measurement (t2) after completion of the intervention. Formative feedback will be requested after each module and summative feedback at t2.

5.2 Research questions

<u>Primary research question:</u>

Q1: Is the guided internet-based intervention "StudiCare Mindfulness" effective in increasing mindfulness compared to a wait-list control group?

<u>Secondary research questions:</u>

Q2: Is the guided internet-based intervention "StudiCare Mindfulness" superior to the waitlist control group in terms of the secondary outcomes depression, anxiety, perceived stress, and quality of life?

Q3: What are the associations between secondary variables, potentially covarying variables (e.g., personality traits, intervention expectations, demographic variables), and the primary outcome? Is there evidence of moderation or mediation of the outcome?

Q4: What is the level of intervention satisfaction, adherence, and acceptance?

6. Study design

"StudiCare Mindfulness" is part of the Barmer GEK-funded StudiCare project at the universities of Erlangen and Ulm (www.studicare.com). In addition to a panel to survey the mental health of students, the project also includes the development and evaluation of Internet-based interventions for students.

"StudiCare Mindfulness" is an Internet-based self-help intervention that will be investigated in a randomized-controlled, two-arm pilot trial (two measurement time points). The study will be conducted in accordance with CONSORT guidelines for effectiveness studies and guidelines for the execution and presentation of Internet interventions (Thabane et al., 2016; Proudfoot et al., 2011). Data collection will take place before (t1) and after (t2) the intervention group undergoes the intervention. Initially, only the participants of the intervention group will have access to the internet-based guided self-help intervention via the internet platform "Minddistrict". One module has to be worked on each week. The module content is based on acceptance and commitment therapy, whose effectiveness in the prevention and treatment of mental disorders has been confirmed in numerous studies (Hayes et al., 2006). The intervention contains a total of five modules. Each module takes approximately 60 minutes to complete. The training elements have an interactive structure and contain texts, images, and audio files. In addition, participants of the intervention group receive feedback from e-coaches via the online platform "Minddistict" after completing the modules. The "Minddistrict" platform also allows participants to have data-protected correspondence with the e-coaches so that questions can be asked and answered at any time. These measures are intended to increase the adherence of study participants and to reduce the dropout rate.

Participants in the waitlist control group will receive unaccompanied access to "StudiCare Mindfulness" after t2.

7. Study population

7.1 Recruitment

The online-based approach of the intervention enables recruitment in the entire German-speaking area (Germany, Switzerland, Austria). The recruitment strategy (regular university-wide sending of recruitment emails at numerous universities such as Ulm, Erlangen-Nuremberg, Rostock, Wuppertal, Basel) has already been successfully applied in the context of two other RCTs in the StudiCare project at the Friedrich-Alexander-University Erlangen-Nuremberg (Harrer et al., 2017; Kählke et al., in preparation). The study will also be advertised with flyers and posters directly at the University of Ulm. All promotional activities will direct to the project website, where detailed information as well as opportunities to contact the study team can be found. After submitting an informed consent, participation in the study can begin. Recruitment will take place via:

- Social networks (e.g. Facebook groups for students of different universities and study programs).
- Website "studicare.com" (an online platform for research and collaborative projects on student mental health, offering various interventions for students)
- Universities (e.g., letters from student councils at various universities and mail distribution lists)
- Psychosocial counseling centers at various colleges and universities (e.g., by writing to them and sending them flyers for the intervention)
- Social contacts of the study team who display flyers at other universities

7.2 Inclusion criteria

To participate in the study, the following inclusion criteria must be met:

Table 1

Inclusion criteria

Inclusion criteria	**Operationalization**
Minimum age 18 years	Self-reporting in online survey
Student status	Self-reporting in online survey
Sufficient knowledge of German language	Self-reporting in online survey
Consent to the study	Returning a signed informed consent
Internet access	Self-reporting in online survey

Medium to low mindfulness	Self-report in online survey by a score in the short form of the Freiburg Mindfulness Inventory (FMI) ≤ 37

7.3 Exclusion criteria

Prospective students will be excluded from the study if they meet the following criteria:

Table 2

Exclusion criteria

Exclusion criteria	**Operationalization**
Current psychotherapy or participation in other mindfulness intervention	Self-reporting in online survey

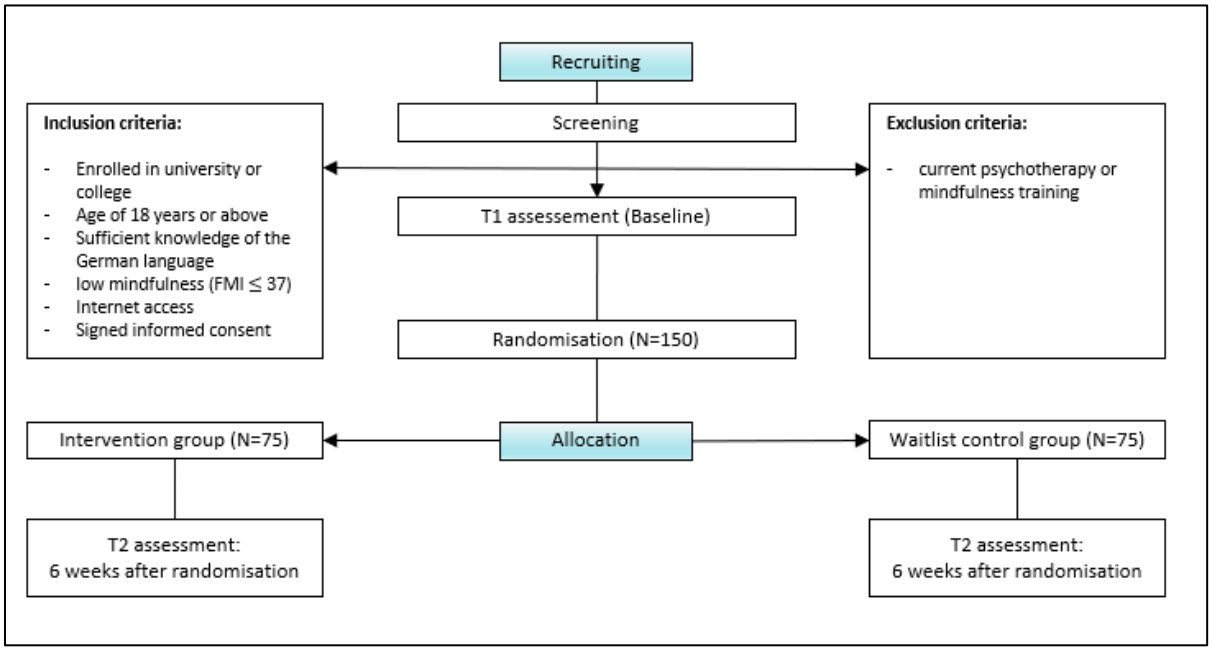
8. Individual course of study

8.1 Study procedure, disclosure and consent

Potential study participants will be recruited via the recruitment channels described above (see Section 7.1) and directed to the study website (http://www.studicare.com/) via a link or QR code. Prospective study participants can register both via a contact form on the study website and directly via the study email address. After contacting us, they will receive an e-mail with a short participant information as well as a link to the entry survey (screening) via Unipark to check the study eligibility criteria. If the eligibility criteria are met, prospective students will receive an e-mail with detailed information on participation and a declaration of consent in PDF format. If participation is desired, the signed consent form will be sent either scanned by e-mail or in a standard letter to the university address of the study team. If the eligibility criteria are met and the declaration of consent is given, the prospective students receive an e-mail as confirmation of participation, including a brief introduction to the online platform. At the same time, they are invited to participate in the first online survey on Unipark (t1). After completing the first survey, participants are randomly assigned to either the intervention (IG) or the waitlist control (WL) group and will be informed about their group assignment via email. Subsequently, the first module is activated as soon as possible for participants of the intervention group, so that they can start the training. The second online survey takes place six weeks after randomization in parallel in both groups (t2). Following the second survey, participants in the waiting list control group also receive access to the unaccompanied training. For an overview of the study procedure, see Figure 1.

The principle of full information is maintained. Prior to the start of the intervention, the prospective participants are informed in detail and in a generally understandable manner in a participant information leaflet about the content, the procedure, the objectives, the possibilities and the limitations of the study. They will be informed that participation is voluntary and that discontinuation of the training is possible and not associated with negative consequences. In addition, the participant information contains an explanation regarding the data protection conditions, the security of the storage and evaluation of the collected data, and the guarantee of anonymity.

Figure 1 Flowchart



8.2 Randomization

Subjects are randomly assigned to the intervention or waitlist control condition using block randomization so that the intervention and waitlist control groups have the same sample size throughout the duration of the study (Schulz & Grimes, 2002). Permuted block randomization is particularly advantageous in successive recruitment. Successively recruited participants are randomized to the intervention and control groups at a randomly varied block length of two or four with a one-to-one allocation ratio per block. The randomly varied block length can avoid selection bias because no inferences can be made about the allocation schedule. The randomization procedure used is the computer-based sealed envelope random number generator (https://sealedenvelope.com/simple-randomiser/v1/lists). The randomization is performed by a research assistant of the University of Ulm, who is not otherwise involved in the study.

8.3 Intervention

The module content of "StudiCare Mindfulness" is based on Acceptance and Commitment Therapy (ACT; Hayes, Strosahl, and Wilson, 1999). The overall goal of the Internet-based mindfulness intervention is to increase students' psychological flexibility, enabling them to better cope with the demands of their studies, experience less stress, and improve their quality of life. Within ACT, there are six key therapeutic processes that are designed to contribute to increased psychological flexibility: being present in the here and now, being accepting and ready, cognitive defusion, clarifying life values, acting with commitment and determination, and the concept of the observer self. These treatment concepts form the theoretical basis of the modules of "StudiCare Mindfulness". Evidence of the effectiveness of "StudiCare Mindfulness" was already shown in a pilot alpha version study on a convenience sample of students (n = 20). Improvement suggestions by the students were incorporated into the current beta version of the intervention.

The online intervention is based on four principles: a) online training: five training sessions with information, in-depth exercises and instructions to improve mindfulness and stress management, b) adherence promotion: sending messages on the training platform reminding participants of module completion if a module has not been completed within seven days. In addition, participants receive automatic mails via Minddistrict when a new module is unlocked. Further principles are c) e-coaching: supervision of participants in the intervention group by study staff (B. Sc. Psychology under close supervision), who provide manual-based, individualized feedback for completed training modules and can be contacted at any time in case of questions (this point is omitted for the unaccompanied version, which the wait list control group receives) and e) exercises in everyday life: homework, instructions and implementation hints to promote a transfer into everyday life.

The order of the modules within the online intervention is fixed and the activation takes place successively after the previous module has been completed. Each module takes about 60 minutes to complete.

Module no.	Module name	Contents of the module
1	Live more consciously in the moment	Introduction to mindfulness; audio file "body scan"; reflecting on the most mindful moment of the day; homework assignment: mindful walk; ACT elements: being present in the here and now, accepting and being ready
2	Seeing stress through different eyes	Mental stress management: Learning about common stress-increasing thoughts and distancing from them; audio files "lemon" and "mindful perception of body posture"; mindful pausing; homework: Applying the distancing strategies, doing a body scan or “mindful perception of body posture” exercise; ACT elements: being present in the here and now, accepting and being ready, cognitive defusion
3	A beneficial thought in your luggage	Finding out what stresses you personally the most; developing a beneficial thought; audio files "Breathing Meditation" and "Internalizing the Positive Thought"; homework: internalizing the positive thought in everyday life; ACT elements: being present in the here and now (especially in audio file)
4	What makes your life valuable	Getting to know individual values; deriving goals from values (SMART formula); audio file "In the here and now"; homework: achieving SMART-formulated goal; ACT elements: clarifying life values, acting with commitment and determination, being present in the here and now
5	Being mindful with yourself: Meet yourself lovingly	Observation and appreciative acceptance of one's own personality; model of personality traits; audio file "Loving kindness meditation": homework: identifying personality traits in everyday life; ACT elements: accepting and being ready, cognitive defusion, observer self, being present in the here and now

9. Benefit-risk assessment

There are no known risks or side effects of Internet-based self-help interventions to increase mindfulness. However, dealing with psychological stress can always lead to negative experiences for a short time. At the beginning of the intervention, it is noted that participants can contact the program's e-coach at any time with questions or concerns. It is also described that the intervention cannot be a substitute for psychotherapy, for whom the intervention is suitable and who should seek therapeutic help instead. In this context, participants are provided with information and links to psychosocial counseling centers, telephone counseling, and psychotherapist locators (German Psychotherapists Association).

10. Biometric aspects

10.1 Questionnaires used and measurement time points

All questionnaires are completed online via the "Unipark" platform. The following table provides an overview of the questionnaires used and the respective time of measurement.

Measuring instruments	**Construct/variable**	**Measuring time point**	
		T1	**T2**
Sociodemographic questionnaire		X	
German short form of the Freiburg Questionnaire on Mindfulness (FMI)	Mindfulness	X	X
Big Five Inventory (BFI-10)	Personality	X	X
Perceived Stress Questionnaire (PSQ)	Perceived stress	X	X
Patient Health Questionnaire (PHQ-9)	Depressiveness	X	X
Generalized Anxiety Disorder Questionnaire (GAD-7)	Anxiety	X	X
Short Form Health Survey (SF-12)	Quality of life	X	X
Patient satisfaction questionnaire (CSQ-8)	Patient satisfaction		X (only IG)
Attitudes towards psychological online interventions (APOI)	Expectations and acceptance (general)	X	X
Questionnaire for acceptance of "StudiCare Mindfulness"		X	X (only IG)

Note: IG = intervention group.

10.2 Statistical formulation and methods of analysis of the research questions

The study follows the CONSORT guidelines for effectiveness studies. Statistical analyses are performed according to the intention-to-treat (ITT) principle. The α-error will be set at $\alpha = .05$ for all calculations. Given conditions, mean comparisons of the primary endpoint (mindfulness) and secondary endpoints (stress, depression, anxiety) will be made between intervention and wait-list control groups at postmeasurement time, taking baseline values into account. In addition, correlations and regression analyses will be calculated. Furthermore, moderator and mediator analyses will be performed if the sample size is sufficient.

10.3 Estimation of the planned sample size

The sample size for the pilot study was determined using G*Power 3.1.9.2. A power analysis for a two-group, two-measurement repeated measures ANOVA based on an alpha error of 0.05 and a power of .9 indicated that a sample size of $N = 120$ was needed to detect an assumed small effect of $f = .15$ (corresponding to $d = .3$). An effect of $d = .3$ for Internet-based mindfulness interventions was found in the meta-analysis by Jayewardene, Lohrmann, Erbe & Torabi (2016). Because Internet-based interventions are expected to have relatively high dropout rates (Bennet and Glasgow, 2009), a dropout rate of 20% is assumed for the present study, which corresponds to 15 additional participants in intervention and control groups. Thus, a total sample of $N = 150$ subjects is targeted.

11. Data management and data protection

All self-report data (at t1 and t2) will be collected online via the questionnaire platform "Unipark". The automatic recording of the number of completed modules as well as intervention logins is done via the intervention platform "Minddistrict". Participants are informed that they can enter an e-mail address without a clear name and a fictitious username for logging into the internet platform "Minddistrict", so that it is not possible to draw conclusions about their person.

Data storage: The data is stored on the bwCloud (bwSync&Share, https://bwsyncandshare.kit.edu). This enables the synchronization of data between different users, desktop computers and mobile devices. The data is stored at the Karlsruhe Institute of Technology (KIT). This service is only available to users of the universities and colleges in Baden-Württemberg. Only designated project staff members are granted access to the data

stored on the bwCloud, which is additionally protected by a password. The data collected during the scientific investigation is treated confidentially and is stored and passed on exclusively in encrypted form. The transmission of data collected on the internet platform Minddistrict is encrypted according to current security standards. The data collected on the Minddistrict internet platform will be stored by the IT provider for a period of 15 years in accordance with current European security standards.

Personal code and coding list: Participants are assigned a personal participant ID that allows to match individual data from Minddistrict and Unipark. There is a coding list that links email addresses and participant IDs. This is required for data collection. The coding list is only accessible to project staff who are sworn to secrecy and is destroyed after data collection is complete. After destruction of the coding list, the data are only available in completely anonymized form. It is then no longer possible to draw conclusions about individual subjects.

Deletion of data: Participants may request deletion of all data collected from them at any time. However, once the coding list is deleted, the data set can no longer be identified. The request for deletion of the data can only be complied with as long as the coding list exists.

12. Ethical and legal aspects

The conduction of the present study is based on the Declaration of Helsinki revised by the 59th General Assembly of the World Medical Association in Seoul in 2008. Furthermore, the European Directive 2001/20/EC for good clinical work and the Charter for Fundamental Rights of the EU (2000/C364/01) are considered. The study received a positive ethics vote from the ethics committee of the University of Ulm after initial submission of the ethics application (application number: 105/17) on 17/05/08.

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