

Study Protocol

Refinement of the *ECHT-intervention* against stigmatization of people with visible chronic skin diseases for further target groups

“Beruf und Gesundheit in körpernahen Dienstleastungen“ (BEGINN)

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1. Synopsis

Short title	Destigmatization of skin diseases in the public
Sponsor	Beiersdorf / Eucerin Social Mission Programme
Collaborators	German Psoriasis Association (Deutscher Psoriasis Bund e.V., DPB)
Research objectives	The objective of this project is to adapt and test the “ECHT-intervention” for feasibility and effectiveness in professions dealing with health and body care (i.e. hairdressers, cosmetologists, nurses, and physiotherapists/occupational therapists).
Study design	A 3-hour-intervention including self-experience/exercises, education and a patient encounter will be developed in an interdisciplinary expert group with patient participation. The evaluation will follow a randomised controlled design against a control group receiving a non-stigma-related intervention. Eligible participants will be professionals from the following branches: hairdressers, cosmetologists, nurses, physiotherapists/occupational therapists. Feasibility and effectiveness with regard to primary (stigmatising attitudes) and secondary outcomes (satisfaction with the intervention) will be assessed at three time points: baseline/before the intervention, immediately after the intervention, 3-month follow-up.
Estimated number of participants	n = 120 (30 per profession)
Outcomes	The main outcome is stigmatising attitudes, which will be assessed by desire for social distance, agreement with skin disease-related misconceptions (e.g. psoriasis myths), agreement with skin disease-related stereotypes, (each adapted from Pearl et al. and reported and intended behaviour towards people with skin disease (Reported and Intended Behaviour Scale (RIBS); adapted from Evans-Lacko et al.). In addition, sociodemographic information, such as age and gender, will be recorded.
Data analysis	Effects will be analysed using mixed repeated-measures analysis of variance.
Benefits	The results of the program will provide new insights and markedly extended knowledge on measures to prevent/reduce stigmatization in visible chronic skin conditions. They will deliver unique data regarding the benefits of structured interventions against stigmatization. Future destigmatization programmes can be based on the outcomes of this project. Key results will be the first data on the effectiveness and benefits of an intervention against stigmatization in these important target groups. The new intervention is expected to be a path-breaking support in the psychosocial health prevention for people with skin diseases. It is in line with the WHO campaign for people-centered health care (PCHC) which is dedicated to improve the situation of people with chronic diseases worldwide [10]. Overall, the deliverable outcome will be an intervention format which can be used in many countries, increasing awareness and acceptance of skin diseases in the public. In total, the project completely fits the purpose and the vision of the Eucerin Social Mission and adds substantial value to the lives of people affected with skin diseases.

Timeline	Overall project duration is three years, including publication and dissemination. Initiation at any time starting with Q4/2021.
Ethics	The study will be carried out in compliance with the Helsinki Declaration and examined by the ethics committee of the University Medical Center Hamburg-Eppendorf.

2. Table of contents

1. Synopsis.....	2
2. Table of contents.....	4
3. Abbreviations.....	5
4. Responsibilities and addresses.....	6
4.1. Coordinating center.....	6
5. Background and objectives.....	7
5.1. Objectives.....	7
6. Study protocol	8
6.1. Study design and procedures	8
6.2. Participants	9
6.3. Outcomes	9
6.4. Data management and statistical analyses	11
6.5. Quality assurance.....	12
6.6. Data protection and ethics	12
7. Timelines and Milestones	13
8. References	15

3. Abbreviations

CVderm	German Center for Health Services Research in Dermatology
IVDP	Institute for Health Services Research in Dermatology and Nursing
T0	Baseline, immediately before the seminar
T1	Post-test, immediately after the seminar
T2	Follow-up, 3 months after the seminar
UKE	University Medical Center Hamburg-Eppendorf

4. Responsibilities and addresses

4.1. Coordinating center

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5. Background and objectives

Approximately 10 million people in Germany suffer from a chronic skin disease.¹ Besides physical symptoms, the psychosocial burden for patients is high.² A specific problem is stigmatization.³⁻⁵ Many sources report that, even today, in Germany the problem of stigmatization is still very burdensome for people with skin diseases. In its resolution of 2014, the World Health Assembly (WHA) stressed the importance of a holistic approach to health care including efforts against stigmatization of patients with psoriasis. Consecutively the World Health Organization in its Global Report on Psoriasis 2016 has explicitly pointed out the importance of reducing stigma.^{6,7} A holistic view and a people-centered perspective are needed to adequately address physical, psychological and social impairments associated with a dermatological disease. To account for stigma-related impairments, evidence-based interventions in chronic skin conditions and their appropriate evaluation for effectiveness and feasibility (e.g. RCT) are highly needed.⁸

A first project to address these needs was a three-year funded project by the German Federal Ministry of Health (BMG; project number: ZMVI1-2517FSB809) 2018-2020 – the “ECHT-project”.⁶ Within this project, face-to-face interventions to reduce external stigmatization were developed in a multidisciplinary group and tested for effectiveness. The target groups were medical students and future educators and teachers. The interventions intended to sensitize them already during their studies or training to the risk of stigma related to visible skin diseases. The evaluation had a randomized controlled design. First analyses have shown that in both groups, medical students and future educators/teachers, the intervention significantly reduced the desire for social distance from people with psoriasis in the intervention group compared to the control group. In addition, the agreements to negative stereotypes and to disease-related false assumptions were significantly reduced in the intervention group but not in the control group. Based on these findings it is essential to further enlarge the target groups for such successful interventions against stigmatization. The vision is to create tools which permit prevention/reduction of stigmatization in a broad spectrum of society, thus adding value to the social mission. Important groups developing and promoting attitudes on stigmatization are professions in the health and body care sector. Some patients with visible skin diseases report feelings of rejection and stigma in such situations. For this, these professions have been chosen as targets of the planned intervention.

5.1. Objectives

This project aims to modify the “ECHT” intervention for health and body care professions and

evaluate its effectiveness. It was hypothesized that the intervention group would show a larger reduction in stigmatising attitudes towards people with visible chronic skin diseases compared to the control group.

6. Study protocol

6.1. Study design and procedures

Cross-sectional interventional study on health and body care professionals (i.e., hairdressers, cosmetologists, nurses, physiotherapists/occupational therapists) recruited in the area of Hamburg, Germany.

Participants will sign up for one of the seminar dates through the study website. Seminars will be randomly assigned to be intervention or control seminar.

6.1.1. Intervention seminar

The intervention seminar will be a modified version of the “ECHT” seminar,^{9,10} consisting of three components: (a) three self-reflection exercises about participants’ own vulnerability to stigmatisation, stigmatisation risk in 24 different dermatological diseases, and participants’ reflection on which skin disease they could imagine living with the best and the least (30 min); (b) a lecture on skin diseases and stigma (20 min); and (c) an encounter with a person with psoriasis who shared their personal experience living with a VCSD with an emphasis on stigmatisation and answered questions of the participants (60 min). Apart from the patient encounter, seminar contents will be skin-generic.

6.1.2. Control seminar

The control seminar will be comparable to the intervention seminar in both structure and degree of required engagement/activity. The focus will lie on the participants’ health in the workplace consisting of: (a) a self-reflection phase, in which participants reflect on their own experiences with physical and psychological stress at work (30 min); (b) a lecture focusing on stress and stress management techniques (20 min); and (c) an e-learning tool on mental health for employees (60 min).

6.2. Participants

6.2.1. Number of participants

According to an a priori sample size calculation using G*Power¹¹ (F-tests for repeated measures ANOVA, within-between interaction) with the effect size obtained by Weinberger et al.¹⁰ (interaction effect for behavioural intentions: $\eta_p^2 = 0.02$), 82 participants are needed to obtain a power of 0.80 ($\alpha = 0.05$). To account for multiple testing and a potential drop-out rate of up to 20% at follow-up, we aim to include 120 participants in total.

6.2.2. Inclusion and exclusion criteria

Eligibility will be checked through self-report. Inclusion criteria comprise:

- being 18 years or older;
- working as a hairdresser, cosmetologist, nurse or physical therapist or being at least in the second year of training for one of these professions;
- being able to consent autonomously and to speak and understand German
- having signed an Informed Consent Form.

6.3. Outcomes

Participants will be asked to report their sociodemographic information and fill in the following self-report questionnaires via the platform Unipark (<http://www.unipark.com>) or using pen and paper at three time points, immediately before (T0) and after (T1) participating in the seminar, and 3 months later (T2):

6.3.1. Primary outcomes

- **Stereotype endorsement**^{9,12}: Agreement to negative stereotypes about people with psoriasis will be assessed using a scale consisting of 11 adjective pairs (e.g., unattractive – attractive). Participants were asked to mark the circle closest to the adjective they

considered to describe a person with psoriasis (range: 1–5). Scores will be averaged, with higher scores reflecting stronger endorsement of negative stereotypes.

- **Disease-related misconceptions^{9,12}:** To measure agreement with common misconceptions about psoriasis, participants will indicate their degree of agreement with 15 statements (e.g., “Psoriasis is contagious.”) on a 5-point Likert scale ranging from “strongly disagree” to “strongly agree”. Scores will be averaged, higher scores reflecting stronger endorsement of these misconceptions.
- **Desire for social distance^{9,12}:** Participants will rate their desire for social distance towards persons with psoriasis in nine situations (e.g., shaking hands) on a 5-point Likert scale ranging from “definitely not” to “definitely”. Scores will be averaged, higher scores reflecting a higher desire for distance.
- **Reported and intended behaviour¹³:** The Reported and Intended Behavior Scale consists of four items assessing the presence of behaviour (yes/no) in each of four contexts (living together with, working with, living nearby, and continuing a relationship with someone affected by a chronic skin disease) and four more items assessing intended behaviour in these contexts in the future, rated on a 5-point Likert scale ranging from “strongly disagree” to “strongly agree”. A sum score across the four “future behaviour” items will be calculated, with lower scores indicating more stigmatising behaviour.

6.3.2. Secondary outcomes

- **Satisfaction with the seminar:** Participants’ satisfaction with the seminar will be assessed at T1 using twelve items addressing general satisfaction with the seminar and its scope, personal and occupational relevance, preparedness for similar situations at work, and whether they would recommend the seminar to a colleague.^{9,10} The statements will be rated on a 5-point Likert scale, ranging from “strongly agree” to “strongly disagree”, with lower scores indicating stronger satisfaction.
- **Blinding to study goal and group membership:** At follow-up, participants will be asked to describe what they thought was the goal of the study and to indicate whether they believed they were in the intervention group, the control group, or did not know which group they belonged to.

- **Port-Wine Stain:** As the intervention content is designed to be skin-generic, the questionnaires assessing stereotype endorsement, disease-related misconceptions and desire for social distance will be administered a second time with a focus on port-wine stain.
- **Emotional Responses:** A subscale of the Desire for Social Distance Scale¹² will be used to assess emotional responses to three images of persons with psoriasis and two images of persons with port-wine stain. Images are standardized with black background, and patients have consented to their images being used for research purposes. Participants will be asked to rate the extent to which they felt six emotions (blame, compassion, contempt, curiosity, disgust, pity) on a scale from 1 = “true” to 5 = “false” in response to the psoriasis and port-wine stain images, respectively.

6.4. Data management and statistical analyses

6.4.1. Data management

The pen-and-paper questionnaires will be returned by the participants to the researchers at the seminar. Data entry from pen-and-paper questionnaires into a SPSS dataset will take place at the CVderm. 10% of cases will be double-checked by an independent data analyst by comparing SPSS data to the original questionnaires, to detect systematic errors of data entry. Data entered online will be exported from Unipark. The full SPSS dataset will be analyzed for plausibility by application of appropriate algorithms. Implausible data will be corrected or defined as missing values.

6.4.2. Statistical analysis

The statistical analyses will be conducted with the Statistical Package for the Social Sciences (SPSS v.27.0; IBM Corp., Armonk, NY). Descriptive statistics, i.e., absolute/relative frequencies and percentages for categorical variables and minimum, maximum, median, mean and standard-deviations for continuous variables, will be obtained for the total sample and subgroups of participants (e.g., by profession). The reliability of all questionnaires will be examined before conducting inference analyses, by calculating the Cronbach’s Alpha coefficients, considering $\alpha \geq 0.70$ as acceptable and $\alpha \geq 0.80$ as optimal.¹⁴ Assumptions of normality and sphericity will be checked by means of Shapiro-Wilk and Mauchly's Test of Sphericity, respectively.

Intervention effects on the primary outcomes will be analysed by means of 2 (Group: intervention, control) x 3 (Time: t0, t1, t2) repeated-measures analyses of variance (ANOVA). Subgroup analyses will be performed to assess potential differences between the professions. Intervention effects on the primary outcomes by profession will be analysed through 2 (Group: intervention, control) x 3 (Time: t0, t1, t2) x 3 (Profession: beauty, nurses, physical therapists) repeated-measures ANOVAs. The significance level will be established at a p-value ≤ 0.05 . Bonferroni correction for multiple testing will be applied. Effect sizes will be reported as η_p^2 , with $\eta_p^2 < 0.06$ indicating a small effect, $\eta_p^2 \geq 0.06$ indicating a medium effect and $\eta_p^2 \geq 0.14$ indicating a large effect.¹⁵ Post-hoc pairwise comparison will be used to further examine significant effects.

6.5. Quality assurance

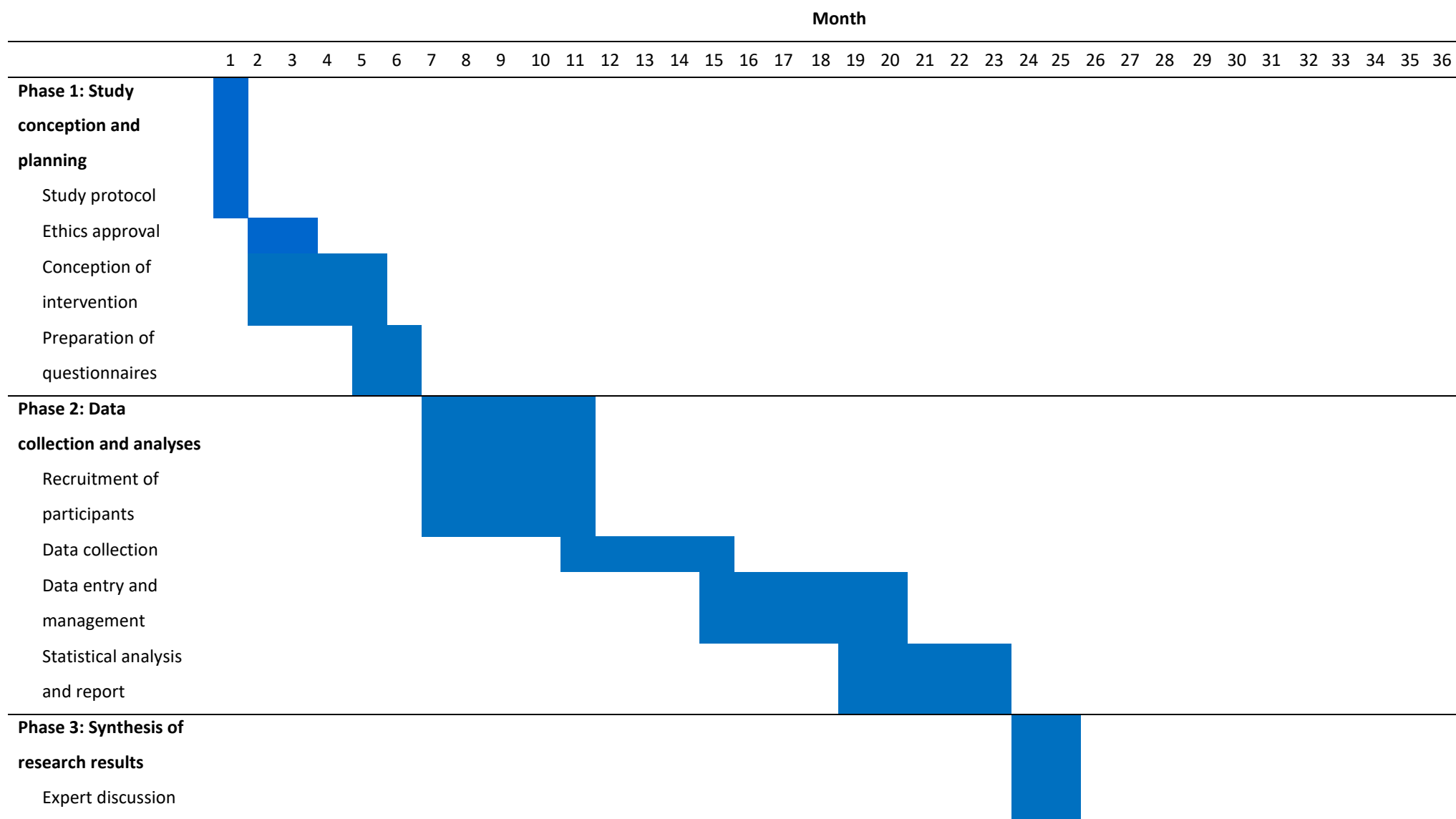
The study will be conducted following the criteria for Good Scientific Practice. CVderm was certified in accordance with DIN ISO 9001 in 2008 and was re-certified in 2013. Furthermore, CVderm follows its own standard operating procedures (SOP).

6.6. Data protection and ethics

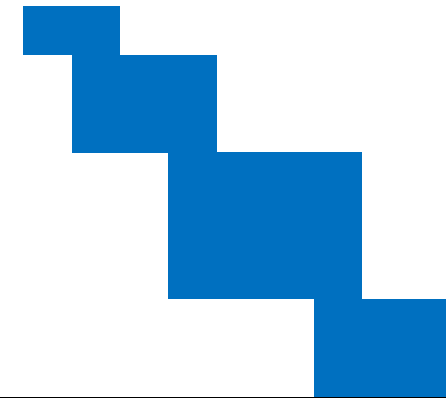
Before implementing this study, it will be reviewed by the ethics committee of the University Medical Center Hamburg-Eppendorf (LPEK).

Participants will receive written information on the study and the opportunity to ask questions prior to giving written informed consent. The questionnaires will be pseudonymized (encrypted with a numerical code so that only the researchers involved in the project are able to allocate personal data by using a key list).

7. Timelines and Milestones



and impact analysis
Interim report and
publications
Dissemination &
Implementation
programme
Final report &
presentations



Final report

8. References

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