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How to personalise cognitive–behavioural therapy for chronic primary pain using network analysis: study protocol for a single-case experimental design with multiple baselines

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ABSTRACT

Introduction Cognitive–behavioural therapy (CBT) is an effective treatment for chronic primary pain (CPP), but effect sizes are small to moderate. Process orientation, personalisation, and data-driven clinical decision-making might address the heterogeneity among persons with CPP and are thus promising pathways to enhance the effectiveness of CBT for CPP. This study protocol describes one approach to personalise CBT for CPP using network analysis.

Methods and analysis A single-case experimental design with multiple baselines will be combined with ecological momentary assessment (EMA). Feasibility and acceptance of the study procedure will be demonstrated on a sample of n=12 adults with CPP in an outpatient clinic. In phase A, participants complete 21 days of EMA, followed by the standard diagnostic phase of routine clinical care (phase B). Person-specific, process-based networks are estimated based on EMA data. Treatment targets are selected using mean ratings, strength and out-strength centrality. After a second, randomised baseline (phase A'), participants will receive 1 out of 10 CBT interventions, selected by an algorithm matching targets to interventions, in up to 10 sessions (phase C). Finally, another EMA phase of 21 days will be completed to estimate a post-therapy network. Tau-U and Hedges' g are used to indicate individual treatment effects. Additionally, conventional pain disability measures (Pain Disability Index and the adapted Quebec Back Pain Disability Scale) are assessed prior, post, and 3 months after phase C.

Ethics and dissemination Ethical considerations were made with regard to the assessment-induced burden on the participants. This proof-of-concept study may guide future studies aiming at personalisation of CBT for CPP as it outlines methodological decisions that need to be considered step by step. The project was approved by the local ethics committee of the psychology department of University Kaiserslautern-Landau (#LEK-457). Participants gave their written informed consent prior to any data assessment and app installation. The results of the project will be published, presented at congresses, and relevant data will be made openly accessible via the Open Science Framework (OSF).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This project addresses the need for a paradigm shift in the treatment of chronic primary pain in an innovative way: it aims to implement a process-orientated data assessment as well as treatment of chronic primary pain.
⇒ The clinical decision-making process is data driven to avoid cognitive biases of practitioners and researchers.
⇒ This project translates person-specific network analysis and single-case experimental design (SCED) into clinical practice, incorporating the patients' perspective.
⇒ SCED results are not generalisable to the group level.
⇒ The lack of gold standards for estimating person-specific network analysis and SCED parameters complicates the determination of treatment targets and effect sizes.

Trial registration number NCT06179784.

INTRODUCTION

Dolores Algae, 60 years old, is one of around 30% of people worldwide living with chronic primary pain (CPP),[1] seeking treatment to relief her pain in her right arm and hand (Note: The case example described in this study protocol is fictitious and does not represent any real case or data). In the absence of a sufficient somatic diagnosis, Mrs. Algae is diagnosed with persistent somatoform pain disorder,[2] or somatic symptom disorder with predominant pain.[3] In accordance with national and international guidelines, she is being referred to cognitive–behavioural therapy (CBT).[1 4 5] That way, Mrs. Algae and her therapist can expect a small to moderate effect on her symptoms.[6–9]

Despite evolving research methods, the observed effects of CBT on CPP did not increase.[6] One plausible explanation is that results of nomothetic studies at group level—such as from randomised controlled trials (RCTs)—might not be applicable to individuals like Mrs. Algae.[6 8 10] For valid nomothetic inference, the data must be 'ergodic', that is, the same statistical model must hold at both group and individual levels and the assumption of stationarity must hold.[11–14] In other words, a group and its components (ie, participants) have to be homogeneous regarding the effect, and there is no variability over time. In human sciences, these assumptions are almost never met.[12 15] As the CPP population is characterised by an especially noticeable heterogeneity, generalisations to the individual might not only be invalid but the observed averaged effects could be impaired by idiographic differences in the effect.[6 16 17]

So, how could Mrs. Algae's treatment be improved? Bartels *et al*[18] argue that person-centred and behavioural interventions are necessary for sustained benefits of CPP treatment across different outcomes.[18] This agrees with calls for a paradigm shift in the treatment of CPP[6 19 20]: Mrs. Algae's treatment should be tailored to her individual circumstances, focusing on therapy-relevant processes instead of mere symptoms,[1] an approach emerging for the treatment of mental illness in general.[21 22] Process-oriented therapy could facilitate the understanding of mechanisms of change, the dissemination of evidence-based strategies, and provide an alternative, more plausible model for aetiology and treatment response than focusing on symptoms and syndromes alone.[21]

New methods for process orientation and personalisation

The requested paradigm shift requires precise and testable models that allow to link treatment procedures to psychological changes.[8] Unfortunately, current models are rather vague about specific, especially temporal, interactional pathways, or the pathways prove to be more complex than proposed.[22 23]

In addition, CBT usually consists of standardised treatment protocols containing several interventions that are applied consecutively to all patients, assuming that within the protocol there will be a suitable method for everyone. By breaking down evaluated treatment protocols into treatment modules, they can be used and tested independently without the necessity to develop entirely new interventions.[24] We define 'module' as the application of a specific intervention, including the necessary psychoeducation, motivation, and consolidation. As in clinical practice, therapists already select single interventions out of protocols for personalising purposes,[6] they should be evaluated separately regarding the effectiveness and functional associations with therapy processes.[21]

Supposing that separate modules exist, Mrs. Algae's therapist would plan therapy by selecting and prioritising one or several modules. To avoid cognitive biases, Mrs. Algae's data should inform the clinical decision-making process.[25 26] A promising approach to personalisation, process orientation, and data-driven decision-making could be the combination of ecological momentary assessment (EMA), person-specific network analysis, and single-case experimental design (SCED).[27]

EMA allows the longitudinal assessment of relevant processes during the patients' daily lives and reflects inter-individual and intraindividual variation over time.[25 28] It is ecologically valid, reduces recall bias and fulfils the requirement of repeated, systematic measures of SCED as well as of time-varying network analysis.[29] There are helpful guidelines to the implementation of EMA in general[30] as well as in clinical,[31] and even pain-specific contexts.[32 33]

Network analysis on the other hand can model interactive processes and could support personalised and data-driven clinical decision-making.[34–36] Person-specific networks graphically depict interrelated phenomena, describing each recorded symptom, construct, or process as 'node', and the links between them as 'edges'. Temporal relationships between two measurement time points can be mapped using autoregressive statistical methods and depicted as arrow-shaped edges in the network; contemporaneous correlations can be estimated using the residuals of the temporal relationships and are represented as line-shaped edges, that is, representing relations within a measurement window.[15 35 37 38] Contemporaneous edges can be interpreted as undirected partial correlations or conditional dependencies, while temporal edges represent predictive, directed relationships over consecutive time points. Both models can be used complementary.[39]

Person-specific networks can guide clinical decision-making by delivering statistical, so-called centrality parameters on the relative importance of each node within the network.[36 40] For contemporaneous and temporal networks, there are different parameters, and the information generated from both can complement each other.[26] An overview of the different centrality parameters can be found, for example, in Hofmann *et al*[36] or Hofmann and Curtiss.[38] In contemporaneous networks, strength centrality equals the sum of the edges' weights of a certain node, giving insights on the overall strength of associations of this node with the others.[28 40] In temporal networks, out-strength centrality shows the degree to which one node predicts other nodes.[40] Centrality parameters are already used in order to interpret person-specific networks,[35] as central nodes are thought to convey information on linked nodes as well,[21] and might thus be promising data-driven treatment targets. Levinson *et al*[41] successfully used centrality parameters to personalise the treatment of eating disorders.[41]

Several research groups developed algorithms to match interventions (like exposure in vivo or relaxation) to assessed symptoms (like avoidance or pain intensity).[10 42–44] Applied to Mrs. Algae's treatment, this procedure would lead to treating the most promising target first with one specific intervention. Later on, Mrs. Algae's network could be assessed again, ideally leading to a new target and recommended intervention. The sequence

of interventions plays an essential role when it comes to personalised treatment.[45]

Finally, SCEDs offer a practical and cost-effective opportunity to evaluate the effectiveness of personalised interventions on the individual level,[46] thus overcoming the problem of non-ergodicity[7 29 47] and ethical issues of waitlist controls.[17] In contrast to RCTs, Mrs. Algae would become her own control by being assessed multiple times in various study phases: Experimental control is achieved by manipulating the treatment onset (independent variable), for example, by randomising the length of Mrs. Algae's baseline phase, and assessing the targeted therapy process repeatedly (dependent variable).[48 49] This experimental control poses a significant advantage over uncontrolled case studies,[50] and the frequently repeated measures ensure internal validity and statistical power.[29]

SCEDs are advocated as a potential bridge between research and clinical practice,[8 49–55] have already been applied in several clinical studies[56–63], and are starting to play an increasingly important role in the field of CPP.[7 17 64–66] SCEDs can be methodologically evaluated using the Risk of Bias in N-of-1 Trials Scale (RoBiNT).[67 68] For an overview of different SCEDs as well as their specific advantages and limitations, see Barlow *et al*,[52] Kazdin,[50] Morley[47] or Vlaeyen *et al*.[55 69] A helpful guide to combined designs can be found in Tanious and Manolov.[70] Tanious and Onghena[48] systematically reviewed the current literature on applied SCEDs regarding designs and application of reporting guidelines.[48]

Objectives

The present proof-of-concept study represents one of the first attempts to evaluate the feasibility and acceptance of a procedure that aims to combine EMA, network analysis, and SCEDs. Data will be collected in an EMA before the start of treatment and the data will be used to estimate person-specific networks. The networks will be used to guide data-driven clinical decision-making regarding treatment target and intervention using an algorithm. Patients and therapists are involved to evaluate the procedure using SCEDs. Evidence of the effectiveness of this personalised procedure will be explored.

Research questions

1. We assume that the implementation of the process-oriented, individualised, network-based therapy for CPP (POINT Pain) is feasible for and accepted by patients as well as therapists. Both aspects are operationalised as mean ratings >3 on a 5-point Likert scale and >1 on a 7-point Likert scale (−3 to +3) in a feasibility and acceptance questionnaire, as well as positive feedback in a semistructured qualitative interview (see the 'Methods' section).
2. Furthermore, we expect POINT Pain to lead to a significant improvement during the intervention phase compared with the baseline phase, that is, a decreasing score in the individual treatment target derived from the person-specific network (see the 'Adapted algorithm' section). This will be analysed visually on the one hand (trend, level) and supported by statistical parameters on the other (see the 'SCED evaluation' section).

METHODS AND ANALYSIS

The procedures of the POINT Pain project have been preregistered on ClinicalTrials.gov (https://clinicaltrials.gov/study/NCT06179784). Additional material is available on the Open Science Framework (OSF; https://osf.io/8xujc/?view_only=c05ad626aa064f6b83d771bfbea0e43e).

Design

An ABA'C multiple baseline design is chosen to evaluate the effectiveness of POINT Pain in an outpatient setting. Multiple baseline designs can be used across participants, behaviours or settings,[49 70] thereby replicating potential treatment effects. In multiple baseline designs across participants, a baseline for each participant is assessed, while the treatment onset for each participant varies.[7] Unlike other forms of SCEDs, the treatment in multiple baseline designs is not withdrawn once introduced.[70] Ferron *et al* discuss the application of multiple baseline designs in detail.[71 72]

First, a baseline assessment (A) is conducted over a period of 21 days six times per day using EMA. The waking hours of the participants (presumably between 9:00 and 21:00 hours) are divided into six equally spaced time intervals and questionnaire prompts are presented semirandomised within each interval. After completion of phase A, a person-specific network is estimated.

Second, a diagnostic phase (B) is initiated. Phase B will comprise 3 weekly sessions, including a first interview, biographical anamnesis (ie, exploration of relevant biographical background like early attachment or learning experiences), and functional analysis (obligatory in Germany for a CBT case conceptualisation, ie, analysis of maintaining factors within a predefined, representative, individual problematic situation). At the end of phase B, participants will be asked to indicate which 5–6 items from the EMA questionnaire they deem to be the most personally relevant. The selection is used to complement item selection for the person-specific network. For the following assessments, up to two idiographic items can be formulated and added to the questionnaire to increase compliance. The assessment protocol is changed to three assessments per week, two during the week and one on the weekend. Prompts are semirandomised during the same times of day as during the EMA. This assessment mode is continued throughout all the following phases.

Third, a second baseline (A') is assessed. Its length will be randomised across participants (multiple baseline design) between 1 and 3 weeks. During phase A', study therapist, supervisor and a researcher of the study management meet for the so-called Algorithm-Guided Intervention Selection Team (AGIST). The process of

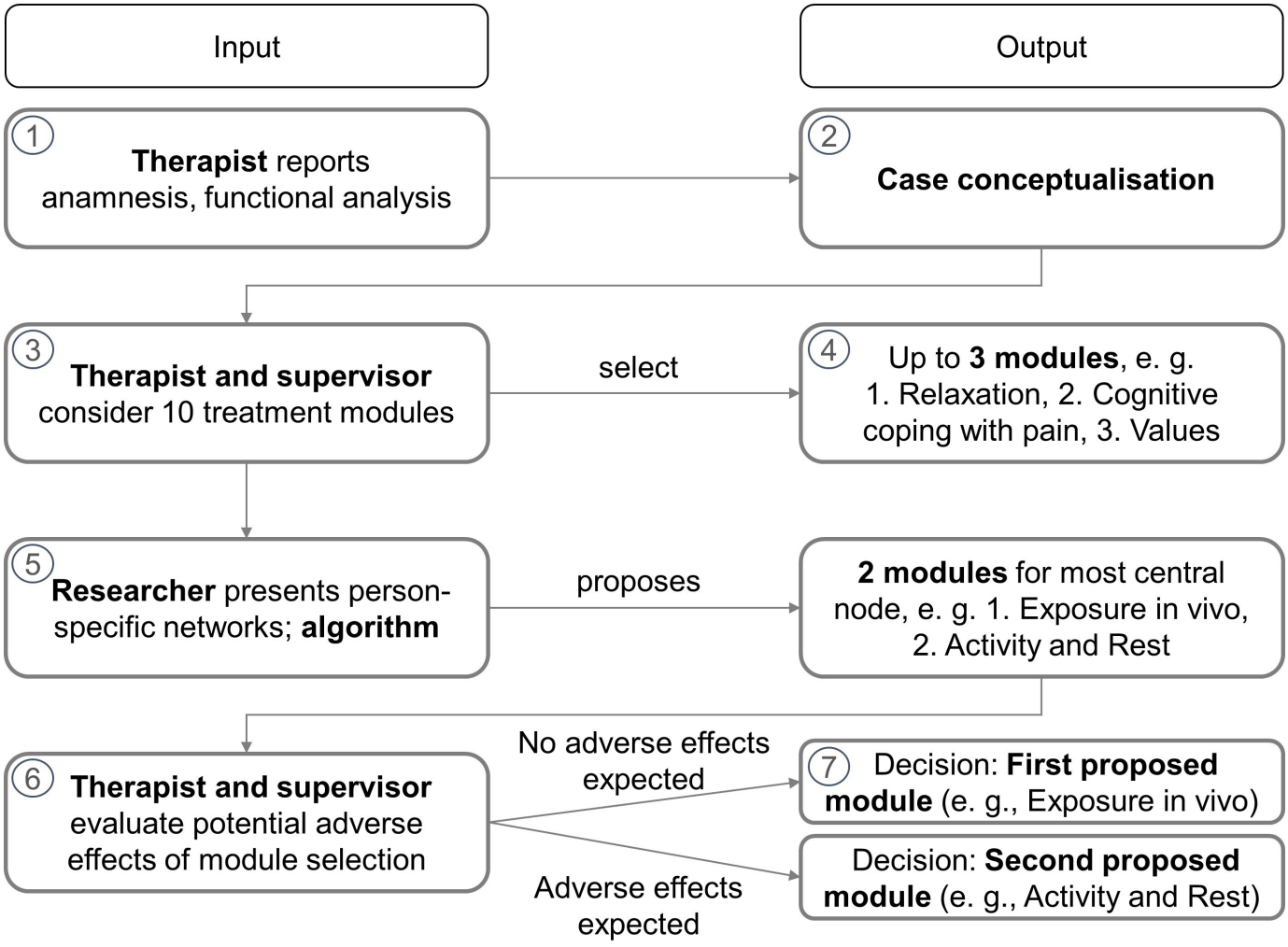

Figure 1 Process of the Algorithm Guided Intervention Selection Team.

the AGIST is depicted in figure 1 and has the following structure:

1. The study therapist verbally presents the information of the diagnostic phase, that is, results of the (biographical) anamnesis and functional analysis, to the supervisor. Neither the study therapist nor the supervisor has knowledge of the person-specific networks and algorithm yet.
2. As a result, study therapist and supervisor develop a mutual understanding of the case conceptualisation.
3. Supervisor and study therapist review ten available treatment modules (see table 1).
4. Based on this review, they select three modules that are considered the most suitable for the case at hand.
5. The researcher presents the person-specific networks as well as the result of the algorithm to the supervisor and study therapist. The algorithm always proposes two modules for each case, based on the averaged centrality of both person-specific networks (see the 'Patient allocation' and the 'Adapted algorithm' sections).
6. Supervisor and study therapist reflect if adverse effects are to be expected for the first recommended module of the algorithm.
7. Supervisor and study therapist decide on the first algorithm option if no adverse effects are expected, otherwise the second option will be applied.

Subsequently, the intervention phase (C) is realised. Sessions 1+2: All participants receive psychoeducation, including motivational aspects. Sessions 3—max. 12: The selected intervention is carried out until significant improvement is reached (see the 'SCED evaluation' section) and maintained over at least 2 weeks, or until a maximum of 10 intervention sessions has been conducted. The 2-week criterion was chosen to ensure that the observed effect was not an outlier (eg, due to holidays or other exceptional circumstances) while remaining within pragmatic time limits, given the maximum therapy duration of ten sessions and subsequent EMA phase.

In a postintervention phase, participants will receive 2 monthly booster sessions for monitoring purposes, while they undergo two additional weeks in SCED mode. Afterwards, another EMA phase of 21 days and six assessments per day will be implemented. Follow-up will take place 3 months after the last session of phase C. The sampling-scheme is summarised in the OSF supplements (https://osf.io/azxeq?view_only=c05ad626aa06

Table 1 EMA questionnaire, constructs and models

Module name	Goal	Exemplary working unit(s)	Adapted from
Exposure in vivo	Correcting beliefs and reducing the recurrence of fear of movement, enhancing activity levels by reducing avoidance behaviour	Developing a movement hierarchy by fear level Performing movements of the hierarchy without avoiding or protection	Nicholas *et al*[121]
Relaxation	Reducing stress and tension that could aggravate pain experience	Practising breathing techniques, progressive muscle relaxation, etc	Kleinstäuber *et al*[122] Kleinstäuber *et al*[123] Nicholas *et al*[121]
Activity and rest (based on pacing)	Balancing activity and rest to enhance flexibility and feelings of control	Activity protocol Activity and rest plan Short practices (eg, stretching)	Main *et al*[124] Nicholas *et al*[121]
Cognitive coping with pain	Reducing rigid, dysfunctional thought patterns Building flexible, functional thought patterns	Thought protocol Cognitive restructuring Metacognitive techniques (eg, labelling)	Kleinstäuber *et al*[122] Kleinstäuber *et al*[123] Nicholas *et al*[121]
Attention control	Enhancing coping with pain, enhancing level of functioning	Antipain diary Distraction alphabet	Kleinstäuber *et al*[122] Kleinstäuber *et al*[123] McCracken[125] Nicholas *et al*[121]
Activating resources	Relief, balancing inconvenient and pleasant experiences	Positive diary Reflecting on healthy areas in the body	Kleinstäuber *et al*[122] Kleinstäuber *et al*[123]
Acceptance	Regaining mental resources, relief	Peace treaty with oneself Disengaging from thoughts	McCracken[125]
Values-based action	Enhancing quality of life, regaining control	Prioritising values Reviewing life	McCracken[125]
Sleep	Enhancing subjective sleep quality and recovery	Stimulus control Imaginary practices (eg, happy place)	Binder *et al*[126] Nicholas *et al*[121]
Self-compassion	Enhancing well-being and feelings of self-worth	Self-compassion break Letter to oneself	Germer and Neff [127] Germer and Neff[128]

EMA, ecological momentary assessment.

4f6b83d771bfbea0e43e). We also rated the study design on the RoBiNT scale (https://osf.io/5p4w2?view_only=c05ad626aa064f6b83d771bfbea0e43e).[67 68] Overall, we reached a conservative rating of 18 (out of 30 possible) points. We fell short on the design as participants do not start assessment concurrently, as well as blinding, which is always hard to achieve in psychotherapy studies. The present study does not contain further replication of the treatment effect, but further research will be planned based on the results. For capacity reasons, the research team also functioned as study therapist in at least four cases, compromising the scores for blinded assessors as well as treatment fidelity.

Participants

In the context of SCEDs, each individual is analysed separately, thus, a sample of n=1 would be sufficient. Regarding the qualitative outcomes (feasibility, acceptance), it can be assumed that a sample of 12 will lead to a saturation in obtainable answers.[73 74] Thus, we aim for a sample of n=12 adult patients with CPP: (1) to evaluate whether the study procedure is feasible and accepted by patients as well as their therapists and (2) to monitor clinically significant change within each individual SCED.

Patients will be recruited via the waiting list of the university's outpatient clinic, contacting licensed physiotherapists and physicians as well as inpatient clinics and via various media (eg, newspaper articles, radio). For patients recruited via the waiting list, screening for suitability will take place during the first consultation at the outpatient clinic. Other patients will be screened by telephone. Recruitment for the project began at 9 November 2023 and was completed at 18 June 2024. As of the date of submission, 15 participants were enrolled in the project. Three dropouts lead to a current sample size of n=12. Data collection is currently ongoing and is expected to be completed in March 2025. The current recruitment status is depicted in the OSF supplement (https://osf.io/z6s3c?view_only=c05ad626aa064f6b83d771bfbea0e43e).

Therapists (licensed CBT therapists or in advanced CBT training) will be recruited via the outpatient clinic.

Inclusion and exclusion criteria

Inclusion criteria are at least 18 years of age, having access to a smartphone (from Android V.5.1 or iOs V.11.0), main diagnosis of CPP (International Statistical Classification of Diseases and Related Health Problems; ICD-10: F45.4x)[2], and subjective pain-related disability. Exclusion criteria are acute conditions of comorbid disorders (substance abuse, psychosis, dangerous underweight, suicidality), migraine, headache or neck pain as only or primary issue, illiteracy, insufficient German knowledge, and physical inability to visit the weekly sessions. German knowledge is assessed via self-report on a 5-point Likert-scale if German is not the first language, with higher values indicating less German knowledge. Insufficient German knowledge is operationalised as values of 4 or higher (ie, 'bad' or 'very bad'). If language barriers are observed throughout the first two assessments with the researcher, participation in the study is carefully reflected within the study management and will be discussed transparently with the participant. Participants cannot parallelly take part in another psychotherapy study or have ongoing psychotherapy or similar treatment. Main diagnosis and comorbid disorders are determined using the German Brief Version of the Diagnostic Interview for Mental Disorders.[75]

Randomisation

As described above, the daily time points of the EMA as well as dates and times of the SCED assessments will be semirandomised within fixed intervals. Additionally, the duration of the second baseline (A') will be randomised between one and three weeks.

Patient allocation

Patients will be allocated to 1 out of 10 interventions (see the 'Intervention' section) according to their treatment target. The treatment target is selected by modelling the six items with the highest mean value in phase A plus up to two subjectively relevant items (asked in phase B) in the person-specific network.

An adapted version of the Dynamic Assessment Treatment Algorithm for Individual Networks (DATA-IN) is used to select the treatment target (see the 'Analysis' section for further details).[44] For all items modelled, strength centrality of the contemporaneous, and outstrength centrality of the temporal network will be averaged, and the item with the highest average score will be selected as treatment target.

The target was used in combination with a matching matrix. It matches two treatment modules to each item of the EMA questionnaire. The matching matrix was constructed following the procedure described by Kaiser and Roth.[43] Briefly, a sample of German-speaking CBT therapists and psychotherapists in advanced training participated in an online survey. They were asked to select up to two most appropriate treatment modules (see table 1) for each item of the EMA questionnaire. Based on their responses, a matching matrix was created, assigning two modules to each item using confirmatory factor analysis. A more detailed description can be found in the OSF preregistration (https://doi.org/10.17605/OSF.IO/BNFWY).

This process of identifying the target based on the person-specific network and assigning treatment modules is referred to as the algorithm.

In the decision-making process (AGIST), the study therapist and the supervisor are presented with the person-specific network, the resulting personal treatment target, and the two intervention choices according to the matching matrix (see above), all of which are analysed before the AGIST by a researcher of the project (see the 'Data analysis' section). Supervisor and study therapist can overrule the algorithm's recommendation only if adverse effects are anticipated (eg, exposure in vivo with existing red flags). The same intervention will be carried out throughout phase C if no adverse effects or non-response over several weeks is observed. Only in case of adverse effects or lasting non-response can the participant be allocated to another intervention, which will be discussed in supervision.

Intervention

10 therapy modules were derived from evaluated CBT protocols that are commonly used in practice and comply to present guidelines. The interventions, their respective goals and exemplary content are summarised in table 1 (also available in the OSF supplements: https://osf.io/hrj94?view_only=c05ad626aa064f6b83d771bfbea0e43e).

If Mrs. Algae took part in the POINT Pain project and went through the first baseline and diagnostic phase, her data might suggest avoidance behaviour as the treatment target, whereupon the algorithm prescribes exposure in vivo as the preferred intervention. As all interventions are constructed in modules, they follow the same structure: At first, an individual explanation model is developed with each patient, considering the person-specific network (eg, fear-avoidance model for Mrs. Algae).[8 76–78] Furthermore, the treatment rationale is deduced from the model and network, and consent for the implementation of the respective module is obtained. After a short diagnostic phase (eg, observing Mrs. Algae's behaviour, developing a movement hierarchy with her), the selected intervention is applied (eg, Mrs. Algae lifts a water box into her car boot). Finally, successes and newly developed strategies should be consolidated and transferred to self-management goals (Mrs. Algae could take on the weekly shopping). The number of sessions to be used for each module segment is not specified to allow for personalisation. In addition, it is left to the therapist to convey the intervention in double or single sessions (single session=50 min). The intervention ends either after 10 sessions or if a significant treatment effect is observed over a period of 2 weeks. The end of the therapy phase (C) will always be discussed in supervision.

Before administering the intervention and interpreting the networks, all study therapists participated in a workshop on SCED and person-specific network analysis. This

ensures that therapists have basic knowledge about the study design and the interpretation of the networks as well as competence in implementing the interventions. Regular supervision enables the timely discussion of specific difficulties in the treatment process (at least every fourth therapy session). All therapists gave their consent to participate in the study and adhere to the procedure.

EMA questionnaire

Although methods of EMA are becoming more popular as technologies and statistical methods evolve, psychometrically evaluated questionnaires for processes relevant to CPP available for the use in EMAs are rare, especially in the German language. At the same time, items of evaluated retrospective questionnaires cannot be applied in EMAs as they do not reflect the necessary variability over time.[79]

Another challenge is the decision which variables to assess in the EMA to adequately reflect the heterogeneity of the CPP population and derive a meaningful explanation model. A pilot study was conducted to develop a set of items that reflects relevant processes in CPP (OSF preregistration: https://doi.org/10.17605/OSF.IO/S4RMN). The resulting items, related processes and their definition, and underlying models of the questionnaire are summarised in table 2 (also available in the OSF supplements: https://osf.io/ea9q2?view_only=c05ad626aa064f6b83d771bfbea0e43e). All items displayed sufficient content validity scores in the pilot study and will be further evaluated qualitatively regarding the patients' perspective (OSF preregistration: https://doi.org/10.17605/OSF.IO/SU9P4) as well as quantitatively in a more comprehensive evaluation study (OSF preregistration: https://doi.org/10.17605/OSF.IO/S4QGP).

To ensure the understanding of each item's wording, an onboarding appointment takes place before the beginning of phase A. In that appointment, the EMA questionnaire is discussed in detail.

Data collection

For all assessments, the software mPath (https://mPath.io/landing/) will be used. The app is installed on the participants' smartphones during the pretest appointment, using a pseudonym as identifier, and a sociodemographic questionnaire as well as the secondary and disability outcome measures will be assessed in the presence of the study management to ensure functioning and settings of the app. From then on, participants receive prompts for the assessment directly on their smartphone, independent from their study appointments. Participants can view their own questionnaire results via the dashboard of the mPath app. Therapists can view the data only of their own patients in a researcher/practitioner dashboard on computers.

Regarding treatment fidelity, video recordings of each therapy session will be carried out for objective data. Additionally, therapists self-report the applied treatment module after each therapy session, using mPath as well. Two undergraduate students independent from the study procedure will analyse the video data based on the procedure described by Leeuw *et al*[80] as well as the self-report data.[80] As the treatment comprises four phases, four recordings per participant will randomly be selected and independently rated by both students.

Primary outcome measures

SCED: The treatment target as derived from the person-specific network and assessed by the EMA questionnaire is the main outcome regarding the effectiveness of the POINT Pain procedure.

Conventional pain measures: Additional to the individual target process, the Pain Disability Index (PDI)[81 82] and an adapted version of the Quebec Back Pain Disability Scale (QBPDS)[83] will be assessed three times: before the EMA (pretest), immediately after the last session of phase C (post-test) and 3 months after the last session of phase C (follow-up). Both measures assess pain-related disability.

Evaluation: To assess feasibility and acceptance of the study procedure, patients as well as therapists will answer adapted versions of the System Usability Scale (SUS; e g, 'I think I would like to use this app frequently.')[84–86] and the User Experience Questionnaire (UEQ-S)[87] in the mPath app. The SUS consists of 10 items using a 5-point Likert scale (1=strongly disagree, 5=strongly agree). The SUS will be assessed twice: once for the mPath app and once for its dashboard. The UEQ-S assesses the subjective impression of the user experience with eight items on a 7-point Likert scale (−3 to +3) on six subscales: attractiveness, perspicuity, efficiency, dependability, stimulation, and novelty.

Additionally, a semistructured interview will be conducted. Patients will be asked about their initial expectations (eg, 'What did you expect at the beginning? Have these expectations been met?'), the onboarding process (eg, 'How can we improve on the onboarding process?'), the practical use of the mPath app ('How did you get on with the mPath app?'), feasibility of the study procedure, including the EMA phases and surveys (eg, 'Would you change anything about the survey, including the frequency of assessments?'), and negative side effects (eg, 'Did you experience any negative side effects? How could negative side effects be reduced?'). Therapists will answer the same questions, completed by the domains clarity of the dashboard (eg, 'Did you use the dashboard? What would you like to change about the dashboard?') and utility for clinical practice (eg, 'Was the app part of the treatment/supervision? What could be changed to maximise its utility?'). Adapted questionnaires and the semistructured interviews are based on the procedure described by Scholten *et al*.[46]

For the POINT Pain project, the semistructured interview will be complemented by questions regarding the presentation of the person-specific networks (eg, 'Was the presentation of the networks easily understandable? What would improve the understandability of the networks?'), acceptance of the algorithm-suggested intervention

Table 2 Constructs and items assessed in the EMA questionnaire ordered by associated psychopathology models

Process	Model	Definition	Item(s)
Catastrophising	Fear-Avoidance/ Avoidance-Endurance[77 78]	Catastrophising describes the tendency to perceive negative aspects of a situation or possible consequences in an excessive manner and to ruminate about or anticipate them[129]	I thought that it will never get better.
			I thought that I cannot go on any longer.
Avoidance		Avoidance constitutes a behaviour aiming at prevention, reduction or termination of the exposure to certain experiences (in pain context: experience of pain[125]	I stopped an activity because of my pain.
			Due to my pain I asked others to do a strenuous activity for me.
			I avoided at least one activity that caused pain.
Depression		A depressive episode is marked by subdued mood and listlessness with a reduction of activity. Even in light forms feelings of guilt and thoughts about the own worthlessness can occur[130]	I felt sad.
			I felt lifeless.
			I felt guilty.
			I felt irritable.
Thought suppression	Avoidance-Endurance[77]	Thought suppression denotes a cognitive reactive pattern that forcefully ends the perception of pain or the disruption of daily activities by pain[77 131]	I thought: 'Hold on!'
			I thought: 'Pull yourself together!'
			I thought: 'Don't make such a fuss!'
			I tried not to think about my pain.
Task persistence		Task persistence describes a physical over-activity that can lead to overuse of bodily structures[77]	I went on despite my pain.
Positive affect		Positive affect marks an emotional state of pleasant mood or feelings that promotes approach oriented behaviour or causes the experience of relaxation, contentment, or serenity[132]	I felt cheerful.
Acceptance	Psychological Flexibility[133]	Acceptance is an embracing attitude that leads to goal oriented behaviour within the personal frame of control as well as distancing oneself from attempts to control unwanted feelings or unchangeable circumstances[133]	I tried to live with my pain.
			I could accept that there is no solution for my pain.
Values		Values are subjectively desirable states that influence behaviour. They include beliefs about what is right and wrong and what is important in life[134 135]	I tried to prioritise those things important to me [individual examples).
Expectations	Predictive Coding[134]	Expectations describe beliefs about what will happen based on previous experiences and likelihood[136 137]	I expected to experience pain in the upcoming two hours.
Pain intensity	Pain Experience[88]	Pain intensity reflects the subjective extent of pain[88]	How strong was your pain during the past two hours (on average)?
Pain-related disability		Disability because of pain describes a limitation in movement, senses, and activities most people can do, caused by pain[138 139]	How much did you feel disabled because of your pain during the past two hours?
Pain self-efficacy[121]	Others	Self-efficacy constitutes the belief to be able to handle even difficult situations successfully and to possess the required abilities[140]	I was confident I could get things done despite being in pain.
			I was confident I could live a fulfilling life despite my pain.
Sleep disturbance[141]		Sleep disturbances include any combination of problems initiating, maintaining, or profiting from sleep[141]	I felt tired.
			Last night, I had problems falling asleep.
			Last night, I had problems sleeping through the night.
			Last night, I woke up too early.
Self-compassion[142 143]		Self-compassion describes a non-judging understanding for one's own suffering, shortcomings or failure. It can be divided in the three facets of self-kindness, sense of common humanity and mindfulness[142 143]	I tried to be friendly to myself.
			I told myself everyone has tough times once in a while.

EMA, ecological momentary assessment.

(eg, 'Did you agree with the algorithm-suggested intervention?'), and the clinical utility of the person-specific networks (eg, 'Did you use the network in therapy? How did you use it?').

Finally, compliance rates of all study phases on the patients' end will be drawn on for implications on feasibility and acceptance. A compliance rate of at least 80% will be considered good.

The selection of outcome measures beyond the EMA questionnaire was based on recommendations by Dworkin *et al*.[88]

Secondary outcome measures

Secondary outcome measures will be assessed at pretest, post-test and follow-up. They are pain intensity (11-point scale), affective and sensory pain description (German short-form McGill Pain Questionnaire),[89] pain coping mechanisms (German Pain Solutions Questionnaire)[90], and pain self-efficacy (German Pain Self-Efficacy Questionnaire).[91] Subjective changes in symptoms will be assessed at post-test and follow-up only, using one item of the Patient Global Impression of Change scale.[88]

Data analysis

All analyses will be carried out using the most current version of software R in RStudio.[92] Data preprocessing used the tidyverse package.[93] Network graphs were generated employing the qgraph package.[94]

Network analysis

For the network analysis, participant data are preprocessed, including calculation of descriptive statistics (mean, median, SD) for each variable. Positive items, such as those measuring positive affect and acceptance, undergo recoding to ensure consistent valence directionality across all items.

The following statistical criteria are used to guide variable selection to ensure robust network estimation[46]: (1) Visual inspection of data for problematic distributions (skewness, kurtosis, outliers), leading to exclusion of highly skewed variables (skewness >3), (2) exclusion of variables with low variance (SD <0.2 for min-max scaled variables), (3) exclusion of variables with high correlation (r>0.9) with others, prioritising the most clinically representative variable if necessary and (4) exclusion of time points with missing data.

With a maximum of 126 data assessments during EMA per person, robust network estimation can be assumed with 3–8 variables.[95 96] The number of items is further reduced based on mean values and personal relevance. Up to six items with the highest mean are included first. Up to two additional items are added if patients indicate further items as relevant.

Hence, a temporal (lag–1) and residual contemporaneous network will be modelled using the package 'graphicalVAR' in R.[97 98] Data are not detrended because assessment spanned only 3 weeks.[97]

Adapted algorithm

DATA-IN is used to determine the treatment target.[44] In the temporal network, the out-strength of each item is estimated by averaging the outgoing associations to other items in the network. In the contemporaneous network, the strength scores are estimated by averaging the associations of the respective items with all connected items in the network. To facilitate interpretation by expressing scores as percentages relative to the maximum network strength, both scores are normalised within each individual. Therefore, each individual score is divided by the maximum strength within the respective networks. The normalised individual strength scores of each node are averaged and serve as an indicator of overall item strength. The item with the highest overall strength is the treatment target that determines the treatment module according to the matching matrix.

SCED evaluation

In line with current practices, monitoring of the treatment effect will be observed in weekly visual analyses of trend and mean[55 99] and supplemented by statistical analyses to make statements about effect size and significance.[100–102] Since there is no clear gold standard for the evaluation of SCED data in research to date, this work is based on the recommendation to consider various statistical parameters in order to obtain more information for the evaluation of SCED data.[100] To evaluate the existence of a treatment effect, the non-parametric baseline-corrected Tau (BC-Tau) will be used.[103] Non-overlap statistics perform pairwise comparisons of baseline and intervention data and then reflect the percentage of data that does not overlap. BC-Tau is, therefore, bounded between −1 and +1. BC-Tau is computed using the R package SingleCaseES (function Tau_BC).[104] The calculation of BC-Tau involves three steps: First, the slope of the baseline trend is tested for significance based on Kendall's rank correlation. If the slope is not significantly different from zero, then no baseline correction is made. If the slope is significantly different from zero, the baseline trend is corrected in a second step using Theil-Sen regression. In a third step, the residuals of the Theil-Sen regression are used to calculate tau. Kendall's rank correlation including the adjustment for ties is calculated according to the recommendations of Tarlow.[103] By conducting a statistical analysis of the significance of a baseline trend, we follow the recommendation in the literature to correct only for theoretically and empirically justified baseline trends.[101]

As a supplement to Tau-U, Hedges' g is used to quantify the magnitude of the effect.[105 106] Hedges' g is a direct estimator of Cohen's d, corrects for unequal sample size (or observations per phase) and for overestimation bias associated with small sample sizes,[105] which makes it very suitable for SCED. Due to the closeness to Cohen's d, comparisons across different outcome measures and to the group design are possible.[107]

Patient and public involvement

Although this proof-of-concept study was not codesigned with patients, they are greatly involved from beginning to end of the study procedure. Involvement starts with the onboarding where participants are asked to give their feedback on the EMA questionnaire.

Participants may indicate variables of particular interest to them that will be taken into consideration as nodes of the personalised network. In addition, participants can formulate up to two idiographic items that will be monitored throughout psychotherapy.

Evaluating the feasibility and acceptability of the study procedure for participants aims to include their interests. Opportunities to improve the treatment of CPP should be explored while limiting the burden on participants (see below). Participants' experiences will be assessed, both qualitatively and quantitatively, at the end of the study. Feedback throughout the study will be welcomed and recorded. Following research projects will evolve from the patients' feedback.

Ethics and dissemination

The study has been accepted by the local ethics committee of the psychology department of University Kaiserslautern-Landau (#LEK-457). Participants receive detailed, written study information at the beginning of the pretest appointment and provide informed consent before proceeding in the study.

The study will be conducted, as far as relevant and applicable, in accordance with the ethical principles and recommendations originating from the Declaration of Helsinki[108] and corresponding to the international guidelines on 'Good Clinical Practice' (https://ichgcp.net/de).[109] The current version of the Declaration will be observed when conducting the intervention, evaluation, and documentation.

As there is no clear recommendation regarding the optimal EMA questionnaire length regarding the induced burden,[32] several measures are taken to reduce the burden that could potentially be caused by the assessments on the participants: (1) The item set of the EMA questionnaire consists of maximally 33 items and items on sleep are assessed only once per day, reducing the item set during EMA to 30 items in 5 out of 6 measurement time points. (2) As soon as possible (phase B and subsequent phases), participants switch to three assessments per week for the SCED, further reducing the potential assessment-induced burden. (3) Throughout the SCED phase, the questionnaire can be answered within a 3-hour time frame so that interference with everyday life is minimised. (4) If necessary, the randomised schedule can be fixed on request. (5) To enhance compliance throughout the assessments, participants generate idiographic items over the course of the diagnostic phase. The items are hence included in the daily assessments. (6) Participants use their own smartphones for data collection, ensuring low-threshold accessibility.[110] (7) The app used for this purpose, mPath, is designed to be intuitive and engaging. (8) By integrating positive items (eg, related to values or positive affect), the aim is to prevent participants from repeatedly focusing solely on negative aspects of their lives. (9) To strike the optimal balance between enabling time-saving responses while avoiding the questionnaire to feel overly repetitive or monotonous, as well as preventing mindless responding, items belonging to the same construct were held together, while the order of the items within each construct was randomised.[30] Single-item measures were always presented first in a randomised order.[10] The EMA procedure was piloted to ensure the assessment-induced burden was reasonable, as recommended by Forkmann *et al*.[79] Participants receive €50 for their general participation and additional €50 for each EMA phase in which they complete at least 80% of the questionnaires, resulting in a maximum financial incentive of €150.

The follow-up assessment was purposefully set 3 months after the last session of phase C so that a subsequent treatment could be started in a timely manner. A booster session with the study therapist is scheduled once a month until the follow-up assessment. If necessary, participants will be referred to subsequent psychotherapy.

Results of this project shall be published in suitable journals. Furthermore, the project is presented at diverse professional congresses, reaching practitioners as well as scientists. Materials and data will be made openly available via the Open Science Framework.

DISCUSSION

The present study protocol aims at evaluating POINT Pain, an approach to personalise CBT for CPP using person-specific network analysis. It combines EMA and SCED methodologies with data-driven clinical decision-making to translate the call for a paradigm shift in the treatment of CPP into clinical practice.[6 18–20 25] The main focus of this study is assessing the feasibility and acceptance of such a procedure on patients' as well as therapists' ends, while simultaneously delivering first insights on the effectiveness on the individual level. The POINT Pain project, thus, paves the way for further research when it comes to compare effects of personalised and process-oriented versus treatment as usual.

To develop a research project combining these many approaches and methods, many decisions have to be made. Often evidence-based gold standards for such decisions are yet missing, beginning with the question which processes to assess. When applying network analysis, there are several possibilities to reduce the data to model person-specific networks, and different parameters on which clinical decisions could be based. Summed up: When translating new methods into clinical practice, balancing innovation, methodological rigour, and pragmatism is an ongoing challenge in the decision-making process, that we tried to tackle:

For example, we decided to partly rely on centrality parameters for the clinical decision-making process,

as they are often considered to give information on the importance of nodes within the network.[36 41 95] Yet, centrality parameters were initially developed in other than psychological contexts, therefore, it is not yet established if they are generalisable to psychometric data.[28] In fact, centrality parameters should be interpreted with caution, as they might not always be clinically relevant, inferences based on centrality parameters can be imprecise[35 38], and might be confounded by highly correlating items that are represented as single nodes in the network.[37] Less central nodes can still represent important treatment targets, for example, suicidality,[26] or because of their importance for functioning levels.[111] We decided to use the mean scores of phase A to reduce the data for the person-specific networks and based the target selection on the averaged centrality of contemporaneous and temporal networks to reflect clinical relevance adequately.

When analysing SCED data to estimate treatment effects, there are numerous, sometimes conflicting, recommendations. Visual analysis is commonly used in SCED research[7 105] and is often recommended to evaluate the treatment process over time.[55 99] However, it has been criticised for its subjectivity.[48] More recent approaches favour systematic statistical analysis of SCED data or at least combining visual analysis with statistical parameters.[7 48]

Despite this shift, there is ongoing debate about which statistical parameters to use. For example, overlap-based measures like TAU-U[112] are sometimes criticised for not accurately reflecting effect sizes, while others argue that they do reflect effect size but not necessarily whether the effect is caused by the treatment.[113] In our study, we chose BC-Tau due to its several advantages[103]: It is robust to autocorrelation, avoids floor or ceiling effects, stays within the conventional bounds of correlation or percentage-based effect size statistics, and provides better baseline trend control with a less conservative method. Additionally, BC-TAU is easy to graph and implement, requires few distributional assumptions, and, like TAU-U, is suitable for designs with limited data points.[103 114 115] It also has adequate statistical power.[101 103 112 114 116]

However, it is important to note that SCED parameters may not fully capture clinical significance. Criteria for clinically significant changes in individual patients are still unclear, as nomothetic gold standards for assessing clinical significance are not easily applied at the individual level.

The Duration-Adjusted Reliable Change Index (DARCI) is a promising method that could be implemented in SCED analysis.[117] It adapts the Reliable Change Index to quantify symptom changes of varying durations in individual time-series data. However, DARCI requires normative data, which is not yet available for the EMA questionnaire used in this study. Also, the Bayes factor (BF) is another evaluation method that quantifies evidence for or against the null hypothesis in Bayesian inference.[118] However, the choice of priors is crucial, as vague priors can lead to non-convergence or unstable estimates. In this case, due to the lack of established assumptions in the existing literature, reliable priors could not be determined. Future research would benefit from a comprehensive overview of available procedures and parameters, with a unified taxonomy, as well as the development of gold standards for idiographic research in clinical practice.

With this proof-of-concept study, data will be generated that might serve to establish priors in the future. Until then, the BF will be analysed exploratorily. Another option to evaluate symptom improvement might be the SD. However, there is currently no gold standard on how many SD reflect 'clinically significant improvement' in SCEDs. Furthermore, the EMA questionnaire used in this study has not yet been fully evaluated, therefore, the responsiveness of its items is unknown. On completion of this study and evaluation of the questionnaire, data on item responsiveness will be available. In this proof-of-concept study, we compensated for these limitations by combining the EMA results with conventional measures (PDI, QBPDS).[82 83] Future research should focus on demonstrating which SCED parameters are relevant for and applicable to clinical practice.

Another challenge is teaching study therapists, who have primarily been taught nomothetic research methods so far, to interpret and use network parameters and SCED. Hayes moaned this already in 1981,[54] and Kazdin[50] and Vlaeyen *et al*[69] still observed this nomothetic focus in the training of psychologists and psychotherapists decades later. Visual analysis, at least throughout the therapy process, might be more intuitive than interpreting unknown statistical parameters. We decided to address this challenge in three ways: (1) starting off with an intensive training comprising an introduction to network analysis, (2) using the first supervision to interpret and discuss the network and resulting treatment target together with a researcher, offering further supervision for clarification if necessary, and (3) conducting weekly visual analyses of trend and mean value of the target process and combining TAU-U and Hedges' g to evaluate the existence of a treatment effect as well as its size.

This study is one of the first to combine EMA, person-specific network analysis, and SCED in chronic pain research. Processes instead of symptoms are focused by assessing a wide variety of constructs derived from evaluated CPP explanation models (see OSF supplements, https://osf.io/ea9q2?view_only=c05ad626aa064f6b83d771bfbea0e43e). Personalisation as well as data-driven clinical-decision making is approached using an algorithm based on person-specific networks. Instead of applying a whole set of interventions within a standardised protocol, each patient receives one module specifically fitting their personal treatment target. Due to the EMA phases as well as the broad inclusion criteria (ie, all pain areas except head and neck/migraine, comorbidities allowed), the ecological validity of this study is arguably high. In addition, the patient and therapist perspectives are considered continuously throughout the study implementation. The

POINT Pain project thus bridges not only the scientist-practitioner but rather the scientist-practitioner-patient gap.

Despite these strengths, the study has also limitations that need to be considered: (1) While group-level data cannot necessarily be generalised to the individual, personalised data cannot necessarily be generalised to the group level.[12] Attempts to aggregate the data from this study across all 12 participants can, therefore, only be exploratory. Results should primarily be interpreted at the individual level. A future scientific goal could be the bottom-up generation of subtypes within CPP[12] by conducting further replications to enable meta-analyses across individuals.[119 120] (2) Due to the fact that participants miss signals in the mPath app, it is possible especially in the SCED phases that the database is reduced. For example, in some cases, the second baseline could not even include three measurement time points, which is considered the minimum.[54] In such a case, the second baseline might have to be extended regardless of the initial randomisation. (3) While efforts were made to incorporate methodological recommendations, certain adaptations were essential for the translation of methods into clinical practice. The decisions outlined, including the selection of processes, data reduction strategies for network analysis, and the utilisation of algorithms to inform clinical decision-making, should be regarded as one among various viable approaches. (4) The primary outcome measure (target process of EMA questionnaire) is not yet psychometrically evaluated and norms and cut-offs are missing. This limits the explanatory power of this outcome measure. For this proof-of-concept study, the treatment effect will be based on a combination of decreasing scores in the target process and conventional measures of pain-related disability to compensate for the lack of cut-offs and norms.

In sum, this proof-of-concept study is an ambitious and promising project that aims at combining various methodological approaches to take the next steps towards personalised, process-oriented, data-driven psychotherapy. Particularly in the case of CPP, the approaches described suggest that treatment effects could be optimised by adequately addressing the heterogeneity of the population.

For our exemplary patient Mrs. Algae that could mean an enhanced involvement in the clinical decision-making process as her data and her own hypotheses on relevant pain processes are considered. Her therapist can rely on an algorithm developed based on experts' ratings, thus minimising cognitive biases involved in the clinical decision-making process. Furthermore, both Mrs. Algae as well as her therapist receive frequent feedback on changes in Mrs. Algae's condition through regular assessments and weekly visual as well as statistical analyses. In the future, such a procedure could facilitate the ongoing clinical decisions like how long to stick to a certain intervention, when to switch to another, and looking at the data regarding which intervention should be the next.

In light of numerous methodological hurdles and the practical implementation complexities in clinical settings, POINT Pain delineates a prospective strategy for harnessing programmes that have been proposed but not yet implemented in practice. Further research is needed to take this and other approaches to the test and develop gold standards regarding the implementation of EMA, person-specific network analysis and SCED altogether in clinical practice.

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Contributors VEH: conceptualisation, methodology, formal analysis, investigation, resources, writing original draft, visualisation, project administration. JAG: conceptualisation, resources, writing review and editing, supervision. FK: conceptualisation, software, formal analysis, data curation, writing original draft. Guarantor: SS: conceptualisation, methodology, software, formal analysis, resources, writing original draft, writing review and editing, supervision. ChatGPT and DeepL were used for language editing on single paragraphs (mainly regarding the most complex subjects of the algorithm and SCED parameters). None of the authors are native English speakers and hoped to improve the precision and understanding of the used language by using AI. Either sentences were translated from German to English by the AI, or already written paragraphs were edited for more precision and shortness.

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