

Innovation in pain management: A case study of using co-design methods during the development of
a relapse prevention intervention

Short Title

Co-design methods for the development of a relapse prevention intervention

Authors

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1 **Abstract**

2 **Background:** Many intervention development projects fail to bridge the gap from basic research to
3 clinical practice. Instead of theory-based approaches to intervention development, co-design
4 prioritizes the end-users perspective as well as continuous collaboration between stakeholders,
5 designers and researchers throughout the project. This alternative approach to the development of
6 interventions is expected to promote the adaptation to existing treatment activities and to be
7 responsive to the requirements of end-users. **Objectives:** The first objective is to provide an overview
8 of all activities that were employed during the course of a research project to develop a relapse
9 prevention intervention for interdisciplinary pain treatment programs. The second objective is to
10 examine how co-design may contribute to stakeholder involvement, generation of relevant insights
11 and ideas, and incorporation of stakeholder input into the intervention design. **Methods:** We
12 performed an embedded single case study and used the double diamond model to describe the
13 process of intervention development. Using all available data sources, we also performed a
14 deductive content analysis to reflect on this process. **Results:** By critically reviewing the value and
15 function of a co-design project with respect to idea generation, stakeholder involvement and
16 incorporation of stakeholder input into the intervention design, we demonstrated how co-design
17 shaped the transition from ideas, via concepts to a prototype for a relapse prevention intervention.
18 **Discussion:** Structural use of co-design throughout the project resulted in many different
19 participating stakeholders and stimulating design activities. As a consequence, the majority of the
20 components of the final prototype can be traced back to the information that stakeholders provided
21 during the project. Although this illustrates how co-design facilitates the integration of contextual
22 information into the intervention design, further experimental testing is required to evaluate to what
23 extent this approach ultimately leads to improved usability as well as patient outcomes in the
24 context of clinical practice.

25

26

27 **Introduction**

28 Only a fraction of intervention development projects are able to bridge the translational gaps from
29 scientific research to clinical practice [1-4]. An important factor for this limited uptake may be that
30 contextual factors, such as stakeholder acceptability or implementation in existing practices, receive
31 little attention during earlier development stages [5]. For example, many intervention development
32 guidelines emphasize the formulation of an underlying theoretical construct and subsequent
33 experimental testing to validate each assumed causal step, but only address implementation and
34 feasibility after the intervention development phase has been completed [6-8]. Consequently,
35 theoretically sound interventions may be discarded due to insufficient attention for crucial
36 translational factors such as low perceived utility by patients or healthcare providers (HCPs),
37 inconvenient navigation, or a discrepancy between the intervention requirements and patients'
38 preferences [9-14].

39 An opportunity to increase the emphasis on these factors is to incorporate co-design
40 methods. Co-design is not only characterized by an increment of knowledge over multiple
41 development cycles [15], but also specifically emphasises empathizing with each stakeholder,
42 integrating conflicting requirements and quickly transitioning ideas to testable prototypes. Co-design
43 differs from other design methodologies in that it involves a range of tools and exercises to optimize
44 collaboration between professional designers and people who are not trained in the design process,
45 such as patients and therapists [16]. Done rightly, co-design brings together different views, input
46 and competences of people with a variety of perspectives to address a specific problem [17, 18]. As a
47 result, this approach should increase the acceptability and integration of the intervention in existing
48 clinical practice by accommodating relevant contextual factors that have been identified by
49 stakeholders in the development process.

50 Although co-design is increasingly adopted in the development of healthcare interventions
51 [e.g. 18-23], prior studies have indicated that effective co-design is not without its challenges. For

52 example, the process of engaging all stakeholders can be time consuming and intensive. This can be
53 particularly difficult in the context of healthcare, because healthcare professionals (HCPs) generally
54 have a high workload [20], and participating patients often do not directly benefit from the
55 development projects, which could negatively influence their motivation and engagement.
56 Moreover, patients, policy makers and HCPs can experience conflicting interests during intervention
57 development projects, because the assumed best possible care is generally limited by finite
58 resources or specific treatment guidelines within a particular healthcare environment [24]. Factors
59 such as these could endanger the main principles of co-design and should be further examined in the
60 context of healthcare [18, 19].

61 **Co-design in the context of chronic pain**

62 In the present project, called the SOLACE project (grant number: SIA RAAK 2014-01-23), we
63 developed a relapse prevention intervention for patients with chronic musculoskeletal pain who
64 participate in an interdisciplinary multimodal pain treatment (IMPT) program. The primary reason for
65 adopting a co-design approach was that despite high prevalence rates of relapse after successful
66 treatment, there is a paucity of available research to explain relapse for this particular population
67 [25, 26]. In these situations, a design based approach may be particularly appropriate, because it
68 allows for new insights to be recursively fed into future development cycles, thereby gradually
69 increase the knowledge base over time [15, 27]. Because patients with chronic pain often experience
70 distrust from their personal and medical environment [29], co-design may also prove effective in
71 empowering patients to participate in the development process and to actively share their opinions
72 and ideas [23, 28].

73 **Objective**

74 To increase understanding of how co-design can be successfully applied in the development of
75 interventions in the healthcare domain, more examples of good practice are needed [13, 18, 30].
76 Therefore, our research question is to what extent co-design practices facilitate the translation of

77 meaningful stakeholder experiences into the design of a healthcare intervention. Our first aim is to
78 provide a detailed overview of all co-design activities that were employed during the course of an
79 example project. Our second aim is to reflect on this overview and examine how co-design may
80 contribute to stakeholder involvement, generation of relevant insights and ideas, and incorporation
81 of stakeholder input into the intervention design. We hypothesized that co-design activities would
82 facilitate the generation of relevant experiences and insights from stakeholders and stimulate their
83 active participation during this project. Consequently, we expected that this would yield prototypes
84 that were aligned with clinical practice and would resonate with end-users.

85 **Methods**

86 ***Design***

87 We performed an embedded single case study [31], in which we analysed and evaluated all co-design
88 activities that were related to the development process of the SOLACE project. Throughout the
89 study, the researchers followed a participatory action research (PAR) approach, which is
90 characterized by active collaboration with the people of interest, rather than only researching them.
91 PAR also emphasizes a respectful cooperation between stakeholders and researchers including
92 collective decision-making and a bidirectional transfer of knowledge over multiple iterative
93 development cycles [32-34], which is in accordance with co-design methods [35]. During each cycle
94 insight is acquired through action (e.g. by letting patients interact with preliminary prototypes),
95 empowerment of stakeholders (e.g. by patient involvement in co-design sessions) and subsequent
96 reflection [32].

97 ***Participants***

98 The SOLACE project consortium consisted of two interdisciplinary multimodal pain treatment
99 centres, the Royal Dutch Society for Physical Therapy, The Dutch National Pain Patient Advocacy
100 Organisation, and four research groups with a respective interest in chronic pain treatment (2), co-
101 design and behaviour change. All consortium partners assisted with the recruitment of participants

102 when this was required at specific co-design activities, including patients and their spouses, HCPs,
103 designers, researchers and students. Three researchers, each from a different research group,
104 formed a core team. This team was responsible for the planning and preparation of the co-design
105 activities. To monitor overall progress, a steering committee was formed, which included
106 representatives of all consortium partners. Ethical approval for this study was granted by the local
107 ethics committee (Medical Research Ethics Committee Zuyderland 16-N-46).

108 **Materials**

109 In interviews and co-creation sessions, the core team adopted various co-design methods, including
110 generative techniques, contextual interviews, system mapping and prototyping. These methods were
111 adopted to facilitate stakeholder participation during key moments in the design process: generative
112 techniques to elicit tacit knowledge and latent needs, contextual interviews to increase empathy,
113 system mapping to develop a comprehensive overview of the acquired data, and prototyping to
114 make ideas tangible and possible to experience. Co-creation sessions included multiple co-design
115 methods and were specifically employed to empower a variety of stakeholders to participate in the
116 design process.

117 **Semi-structured contextual interviews.** At various time points in the project, we interviewed patients
118 and HCPs. The interviews were performed by two researchers and were conducted in the everyday
119 context of the HCPs (treatment facility) and patients (at home). To activate prior knowledge and
120 experiences, all participants received 'sensitizers' – assignments that stimulated thinking about
121 relevant topics – before the interview (see figure 1.2) [36]. During the interview, the primary
122 interviewer explored participants' beliefs, needs and experiences using open questions and various
123 generative techniques. The second interviewer took notes, and asked additional questions to ensure
124 that all topics were covered that the research team identified during preparatory sessions. Data were
125 collected by audio recording and notes taking. Directly after the interview, both interviewers
126 discussed their impressions and updated their notes.

127 **Generative techniques.** To explore participants' ideas, needs and values beyond their first response,
128 various generative techniques were employed during interview and design sessions. These
129 techniques aim to bring up 'tacit knowledge' by addressing social, emotional and functional elements
130 related to a topic of interest [36]. For example, to promote a more personal acquaintance during the
131 interview sessions, participants were asked to introduce themselves by selecting three pictures from
132 a deck of cards illustrated with ambiguous images that symbolized their personal values. The core
133 team also used journey mapping during interviews (see figure 1.2). This technique enabled all
134 attendees to collaboratively construct a graphic visualisation or a timeline that illustrates their
135 experiences with IMPT [37, 38].

136 **Prototyping and Provotyping.** A key element of PAR is to increase insight by reflecting on actual
137 interactions with prototypes. As figure 1.3 illustrates, the interaction with these objects stimulated to
138 envision future possibilities or to visualize concept ideas. The process of prototyping allows
139 participants to actively engage with objects that were based on preliminary outcomes and
140 encompass operationalisations of the concept of interest [39]. Provotyping takes place with objects
141 that are not directly related to the final result, but are specifically designed to test a specific
142 hypothesis or elicit a particular response [40].

143 **System maps and personas.** System mapping is a method for creating a visual representation of
144 interacting variables that facilitates the understanding of complex systems [41]. System maps
145 typically include a framework of interrelated components, as well as clarifying examples of quotes
146 and pictures. These maps can be presented in posters or cards and are useful to share data to
147 stakeholders in an accessible way (see figure 2.2). Moreover, it provides participants with the
148 opportunity to jointly reflect on the data and update ideas during co-creation sessions.

149 A specific way to represent the data as a coherent 'whole' for usage throughout co-design
150 activities is by creating personas: fictitious archetypes of users, each reflecting a distinct pattern in
151 goals, attitudes and behaviours, based on empirical research among potential users. With personas it

152 is possible to highlight certain areas of tension or to facilitate discussion of important patient
153 characteristics [42].

154 **Co-creation sessions.** We used co-creation sessions at key moments during the project to discuss and
155 reflect on the collected data, to generate new ideas, and to make decisions regarding future
156 development directions (see figure 2.4). A typical session would take 4 hours and involved ten to
157 twenty stakeholders. The core team prepared the sessions by formulating desired outcomes, and
158 setting up system maps to present the data. During the sessions, two designers operated as
159 workshop facilitators and used various assignments (e.g. prioritizing ideas for prototype concepts) to
160 work towards the desired outcomes in an open atmosphere where everyone was invited to actively
161 participate. All written session data (e.g. posters, drawings, notes) were collected and discussed
162 during core team evaluation meetings directly after the session. To maintain involvement and
163 commitment between the sessions, the core team sent bi-monthly newsletters and posted updates
164 on the project websites.

165 **Measurements and analysis**

166 **Dataset.** The dataset for this case study consisted of four different sources. To capture the results of
167 the design methods, researchers documented each design and research activity, using observation
168 notes, pictures, audio files, and/or video clips. In addition to the session documentation, researchers
169 also organized reflective sessions directly after a co-design activity to summarize the output of co-
170 creation sessions (e.g. notes or post-its) into system maps. These maps served both as a descriptive
171 analysis of the data as well as for input during subsequent co-design sessions. The dataset also
172 consisted of minutiae of steering committee meetings and a retrospective project journey. This
173 journey was the result of a reviewing session, where researchers and members of the steering
174 committee chronologically described and discussed critical incidents.

175 **Data analysis.** We used a deductive content approach to identify information within the dataset that
176 relates to our main themes: stakeholder involvement, generation of insights, and incorporation of

177 stakeholder input. We defined stakeholder involvement as the commitment to participate in the
178 development project, to collaborate with other stakeholders during design activities and to actively
179 participate during these sessions. Generation of insights referred to the extent by which co-design
180 activities resulted in an increased understanding of the problem of interest that could inform
181 subsequent development activities. Incorporation of stakeholder needs was defined as the extent by
182 which prototypes were based on stakeholder perceptions, judgments and evaluations from co-design
183 activities. Furthermore, we adopted the Double Diamond model (DDM) to describe the design
184 process along four development stages [Design 43]. The DDM contains two sequences of diverging
185 and converging. In diverging phases, choice options and discrepancies are created, in the converging
186 phases these ideas are refined and considered to make design choices with respect to the prototype.
187 In the first diamond, the 'Discover' (diverging) and 'Define' (converging) phase relate to acquiring
188 insights on *what* to design. In the second diamond, the 'Develop' and 'Deliver' relate to further
189 exploring the ideas on *how* to optimally design the final concepts. To illustrate how co-design
190 contributed to the intervention development at each phase, we combined all data sources to provide
191 both a descriptive overview and an in-depth reflection with respect to our main themes. In addition,
192 figure 1 provides a chronological overview of the development process and includes examples of co-
193 design methods, data segments, and pictures of co-design activities.

194 [insert figure 1: double diamond model]

195

196 **Results**

197 ***Phase 1: 'discover'.***

198 *Description.* In the 'discover' phase we aimed to generate a deeper understanding of factors
199 influencing relapse after successful rehabilitation. The primary activities took place over a period of
200 11 months and consisted of three kick-off sessions, twenty stakeholder interviews (12 HCPs; 8
201 patients) and a student design project. In the first kick-off session, representatives from all
202 consortium partners were present to discuss the project planning and to decide how co-design would

203 be implemented throughout the project. Representatives also participated in co-creation by using
204 their professional and personal experiences to formulate initial ideas on relapse (see figure. 1.1).
205 These activities were repeated during introductory visits by the core team at the two participating
206 pain treatment centres. During these visits, the core team also observed multiple treatment sessions
207 and were given a detailed explanation about dose and content of the included treatment modalities.
208 Subsequently, twenty semi-structured interviews of approximately 1 hour were conducted and
209 transcribed (see figure 1.2). During the final activity of phase 1, sixty students, divided over sixteen
210 teams formulated hypotheses based on the previously collected data and designed provotypes to
211 test their ideas on both healthy participants and patients with chronic pain (see figure 1.3). At the
212 start of each week, they updated their provotypes based on the received feedback. During the final
213 project session, all teams presented their final provotypes as well as their collected insights to
214 members of the consortium.

215 *Reflection.* In phase 1, we were able to create a large qualitative dataset. This dataset not only
216 contained experiences and ideas of stakeholders, but also included specific feedback in response to
217 multiple provotypes on a wide array of topics. The consecutive planning of the three key activities
218 enabled us to iteratively expand our insights on relapse after pain treatment: Interviews were
219 prepared by using the insights from the kick-off sessions, and the student teams could build upon the
220 preliminary analysis of the available interview data. The participating stakeholders responded
221 positively to the co-design approach and cooperated actively during the sessions and the interviews.
222 Despite their inexperience with co-design, the sessions were considered accessible, pleasant, and
223 relevant. However, medical ethical screening procedures and personnel deployment planning limited
224 the possibility for last minute requests or invitations for including HCPs and patients. The obtained
225 dataset of patient and HCP responses also contributed to a deeper understanding of relevant factors
226 related to relapse, which provided a solid base for further intervention development. For example,
227 the interviews revealed important contextual information such as a 'feelings of emptiness after

228 treatment', 'difficulties to share treatment experiences to friends and family' and 'the different
229 context between the rehabilitation centre and the personal environment'.

230 **Phase 2: 'define'.**

231 *Description.* The 'define' phase lasted for one month and started with thematically organising the
232 interviews by means of open coding by the core team (see figure 2.1) [44, 45]. This resulted in eight
233 main themes and 45 subthemes of factors associated with relapse after successful treatment (see
234 figure 2.2). To facilitate subsequent co-design activities, the themes were rephrased as questions,
235 plotted on posters and illustrated with exemplary quotes and figures (see figure 2.2b for an
236 example). In addition, the core team developed a set of 74 stimulus cards, that were designed to
237 facilitate the discussion of specific insights or principles [46]. 36 cards contained insights from the
238 student project, 15 cards contained relevant theory on behaviour regulation, and 23 cards contained
239 theory related to chronic pain treatment (see figure 2.3). Subsequently, patients (4), HCPs (4),
240 researchers (9), designers (6) and students (3) were invited for a co-creation session (see figure 2.4).
241 During the first assignment, participants were asked to examine the posters and extend them with
242 their own ideas or with stimulus cards. This resulted in 121 notes and 42 cards that were added to
243 the posters. In the second assignment, subgroups were made of participants with varying
244 backgrounds. Each group was instructed to select one theme and use the available information to
245 develop an intervention concept. A professional draftsman supported the session by immediately
246 visualizing intervention ideas. The final part of the session consisted a plenary session where all five
247 concepts were presented. During the subsequent discussion, the concepts were compared and
248 various overarching topics emerged, including 'maintaining the positive development after
249 treatment' and 'reflection and self-monitoring'. In a subsequent meeting, the steering committee
250 merged these overarching topics into two concept ideas: 'positive reinforcement' and 'direct
251 feedback'. The define phase concluded with a design briefing, where the core team commissioned

252 three students to develop these ideas into tangible rudimentary prototypes as part of their
253 graduation project.

254 *Reflection.* The final system map that included both posters and the card set, provided a complete
255 overview of the collected data. This presentation form stimulated participants to combine various
256 insights to develop concept interventions. With respect to stakeholder involvement, the number of
257 patients and HCPs was lower than originally planned. The duration of the session and the traveling
258 distance required participants to block a full day, which turned out to be difficult to organize. In line
259 with our findings in phase 1, the co-design methods successfully engaged non-experts in the design
260 process. The assignment to create concept intervention ideas was concrete and tangible. The
261 resulting five concepts were associated with earlier identified patient needs, grounded in contextual
262 information and contained relevant insights on relapse prevention. For example, one concept idea
263 focused on monitoring and recognizing early signals of relapse, which was based on stimulus cards
264 (e.g. a research insight related to difficulties in unbiased self-monitoring of behavior), interview data
265 (e.g. a quote from HCP on the possibility of daily feedback via eHealth) and newly added notes (e.g.
266 patient feedback should always be related to patient-specific goals). However, only a fraction of the
267 possible combinations of cards and system maps were explored during this session. Limited time and
268 resources prevented organising additional sessions to cross-validate the results and to achieve
269 saturation.

270 **Phase 3: 'develop'.**

271 *Description.* During the 4 months of the develop phase, students held five focus groups to regularly
272 test their ideas with patients and HCPs (see figure 3.1). For example, by discussing the role of
273 personal values within the treatment program, the students found supporting evidence that these
274 values were strongly related to treatment goals, which subsequently guided the operationalisation of
275 the valued-based action plan in one of the rudimentary prototypes. Based on stakeholder feedback
276 and weekly evaluation sessions with the core team, the students worked towards a final rudimentary

277 prototype. One student focused on the transfer of important treatment insights to each patients'
278 personal context. She developed a toolbox that contained various methods to capture and store
279 therapy insights in order to facilitate retrieval in a relevant personal context (e.g. using a personal
280 picture as memory cue for an important moment during treatment). The other two students focused
281 on the generation of valued-based goals and the formulation of action plans for each consecutive
282 step towards the goal. Their final rudimentary prototype consisted of a mockup mobile application,
283 allowing participants to browse through all steps that were required to formulate and plan a valued-
284 based goal. Figures 3.2 and 3.3 show the final versions of these rudimentary prototypes.

285 *Reflection.* This phase was characterized by a shift from 'what' to 'how' to design. Accordingly,
286 presentation form, usability and implementation into existing treatment practice became
287 increasingly relevant. To engage stakeholders, the students visited the treatment centers on multiple
288 occasions. In contrast to other phases, the patients and HCPs could provide feedback on ideas, but
289 were not involved in the decision-making process regarding the final design of the rudimentary
290 prototype, which potentially influenced their commitment. Moreover, their reduced involvement in
291 this phase resulted in limited information regarding the applicability of the rudimentary prototypes
292 in clinical practice.

293 **Phase 4: 'deliver'.**

294 *Description.* In the final phase, the core team merged both rudimentary prototypes into one final
295 prototype intervention over a period of 2 months. To do so, the core team organised a final co-
296 creation session, where the students presented their concepts. The aim of this session was to receive
297 final feedback on the potential value and function of both rudimentary prototypes and to formulate
298 a recommendation to the steering committee with respect to the final prototype design. To facilitate
299 this process, stakeholders (n = 14) were instructed to reflect on the concepts by taking various
300 patient perspectives into account. For this purpose, four personas were created with variation on
301 two characteristics that were often discussed during previous patient interviews. Each persona had
302 either a high or low level of social support and a high or low tendency to protect personal

303 boundaries. Figure 4.1 depicts the discussions between stakeholders as well as the poster that
304 explained the four personas. The final conclusion was that both rudimentary prototypes had
305 potential as supportive treatment modalities to prevent relapse after successful treatment.
306 Furthermore, future testing and development should primarily focus on optimizing the active
307 treatment components and calibrating the intervention to the treatment program.

308 Based on this advice, the steering committee decided to merge both rudimentary prototypes
309 into one prototype workbook. The core team composed a list of individual intervention components
310 from each rudimentary prototype (e.g. a prompt to set calendar reminders after a goal-setting
311 procedure) and coded these according to the Behaviour Change Technique Taxonomy V1 (see figure
312 4.2) [47]. Subsequently, they determined how to transfer the components to a workbook version and
313 performed literature searches to find ideas for optimizing the effectiveness of each component. For
314 example, to assist the formulation of personal values, various value generation procedures were
315 found [e.g. 48] and integrated into the prototype. In addition, the core team checked to which extent
316 the list of intervention components corresponded with the themes of the interview dataset.
317 Seventeen of the 19 intervention components were related to one or more themes from the dataset,
318 and 27 of the 45 themes were related to one or more intervention components. For example, four
319 components in the goal-setting intervention, including specific probing questions to help formulate
320 meaningful values, were associated with the theme 'remembering important goals and values after
321 treatment'. A designer, a text editor and three HCPs provided feedback with the conversion to a
322 paper workbook intervention and respectively focused on the design, readability and appropriate
323 terminology. Figure 4.3 shows examples of the two included strategies: the value-based goal forms (b
324 and c) and the Insight Cards (d)..

325 *Reflection.* Previous difficulties with recruiting sufficient patients for co-creation sessions caused us
326 to search for alternative ways to include their viewpoint. The personas proved a useful method to
327 incorporate various patient perspectives by proxy during the evaluation of the rudimentary

328 prototypes. Furthermore, the validation check indicated that the majority of the intervention
329 components could be traced back to the original stakeholder themes from the interventions in the
330 'discover' phase and vice versa. This illustrates that stakeholder input has been incorporated in the
331 design. However, the decision to combine both prototype ideas into one intervention was
332 unexpected, which resulted in last minute planning and consequently in limited stakeholder
333 involvement during the design of the workbook. This may threaten the usability of this prototype in
334 clinical practice.

335 Discussion

336 337 **Summary of principal findings**

338 The primary aim of this study was to reflect on the value and function of co-design methodology
339 during the development of an intervention that prevents relapse after successful pain treatment. In
340 the analysis, we focused on idea generation, stakeholder involvement and the incorporation of
341 stakeholder input within the development process. Overall, the generative techniques that were
342 employed, supported patients and HCPs with sharing their perspectives on pain treatment and
343 relapse, which was in line with our hypothesis. Moreover, the techniques steered the conversations
344 beyond stakeholders' primary responses, often resulting in a detailed account of their personal
345 experiences with the treatment program and of their attempts to integrate treatment insights into
346 their personal environment. In addition, system maps, personas and prototypes enabled non-experts
347 to actively participate in design activities. A possible explanation for the successful engagement of
348 stakeholders during the project is that experienced co-designers constantly translated hypotheses
349 and abstract ideas into provotypes or prototypes. This method is particularly useful to provoke user
350 reactions or to rapidly visualize an idea, which evokes interactions with an actual object rather than
351 reflections on past experiences of hypothetical situations [39]. In addition, the used co-design
352 materials helped to transform each location where co-design activities took place (e.g. treatment
353 facility or patient home) into a workshop environment that stimulated active participating and

354 emphasized equality between all participants. This is especially important for healthcare settings,
355 where conventional power relationships between patients and HCPs threaten effective cooperation
356 during design activities [18, 19].

357 With respect to stakeholder involvement, many different patients, HCPs, researchers,
358 students, and designers participated during the study, which was also in line with our hypothesis. The
359 stakeholder interactions mostly consisted of independent design activities that required low
360 commitment and little effort. In contrast, the members of the core team remained active throughout
361 the project, which increasingly created an imbalance in knowledge and involvement between the
362 core team and other participants in co-design activities. This may explain why the role of the
363 stakeholders gradually shifted from 'user as partner' – where all participants within the sessions
364 contributed as equals in the design activities – towards 'users as subject' – where participants mainly
365 provided expert opinions or performed delimited tasks (e.g. usability testing) [49]. Consequently, the
366 concepts underlying the intervention have been thoroughly grounded in stakeholder input and
367 expertise, but the applicability of the current workbook operationalization within the treatment
368 programs requires further testing to examine whether the current strategies fit patient preferences
369 and can be integrated in treatment programs in the form of the current prototype.

370 This project shows similarities to the experience-based co-design (EBCD) approach, which
371 aims to improve healthcare services by actively involving stakeholders to collect knowledge and
372 experiences, to set priorities and to develop solutions. Although this project did not follow the six
373 stages of EBCD, the overall objectives as well as the systematic partnership with patients, healthcare
374 providers, designers and researchers are alike. A notable difference was the focus within this project
375 on actual prototype development throughout all phases, which promoted a solution-focused
376 orientation for the participants. Alternatively, in EBCD more emphasis is placed on ensuring that the
377 collected patient experiences are received and understood by other stakeholders (e.g. by showing a
378 film of patient interview segments that reflect key themes), before continuing to developing

379 improvements. These differences illustrate the versatility of co-design and its potential to adapt to
380 different design environments.

381 **Strengths and limitations**

382 The extensive documentation of the co-design activities allowed for a detailed reconstruction of the
383 development process. Furthermore, during co-creation sessions, steering committee meetings and
384 the construction of the retrospective journey, representatives from all research groups were present,
385 which resulted in a continuous integration of various perspectives during the project. However, we
386 did not film or record any of the co-creation sessions. Although analyzing audio or video would have
387 been time consuming, it would have provided further possibilities to observe stakeholder discussions
388 during design activities and to include additional insights that we did not record.

389 During the project, we experienced a tradeoff between validating the outcomes of co-design
390 activities and analyzing the results for the next iteration. For example, an additional co-creation
391 session during the 'define' phase with different stakeholders could have cross-validated the
392 outcomes of the initial session. However, given limited resources, this would have resulted in fewer
393 development iterations in the remaining period. A key argument in favor of more iterations is that
394 quickly integrating stakeholder input into subsequent sessions directly visualizes the value of their
395 input [50]. However, a tendency towards more iterations increases the uncertainty to what extent
396 the outcomes of this project can be generalized to the population [33].

397 **Future recommendations**

398 This study adds to the increasing number of initiatives that use co-design to structurally integrate
399 contextual factors into the development of healthcare interventions [e.g. 21, 22], which help bridge
400 the gap from development to actual implementation [12, 13]. When using co-design, it is important
401 to relate the findings of the process to existing theories and treatments, for instance by using the BCT
402 taxonomy [23, 47]. This strengthens the co-design approach by combining stakeholder evaluations
403 with existing theory. Importantly, a further integration between co-design and theory-driven

404 approach only becomes possible when using rigorous testing to evaluate the outcomes of the co-
405 design process [13]. Consequently, an important next step in answering the question about whether
406 co-design helps inform the development of health interventions, will involve more examples of
407 development projects. In these examples, ideally co-design-based interventions are subjected to
408 experimental testing. Furthermore, we believe that future co-design projects in the healthcare
409 domain should include detailed planning of activities and take lengthy medical ethical approval
410 procedures into account [51].

411 **Conclusions**

412 To acquire a better understanding of how co-design may benefit the development of interventions in
413 the healthcare domain, examples of good practice are necessary. In this article, we presented such
414 an example. By critically reviewing the value and function of a co-design project with respect to idea
415 generation, stakeholder involvement and incorporation of stakeholder input into the development
416 process, we demonstrated how co-design contributed to the transition from ideas, via concepts to
417 prototypes.

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422

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