

SUPPLEMENTARY FILE

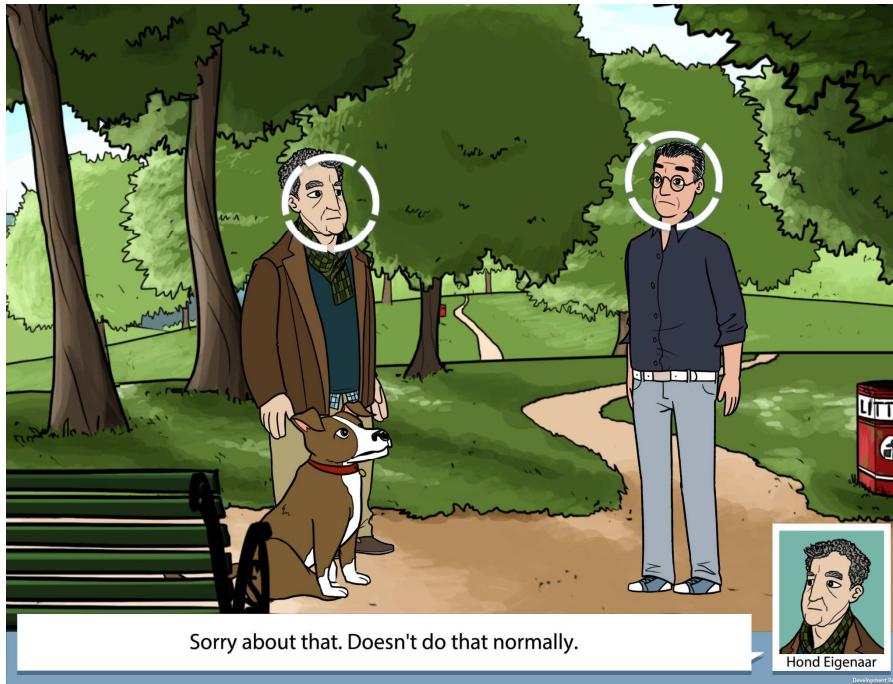
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1. *Developer assumptions*

Developer assumptions	Related theory (interpretation)
<p>The rehabilitation program is based on a (four dimensional) bio-psycho-social-spiritual treatment model in which Eastern and Western (medical) interventions are integrated. Interventions are aimed at improving ‘mobility of mind’, which is defined as: flexibility in accommodating 2 dynamic processes: 1) participation in private, social, and work roles, and 2) the ability to participate. Ability to participate depends on four interdependent aspects: symptoms (signals due to organ system injury or disturbance in shaping and controlling one’s life or ‘existence’), autonomy, perspective (‘to see one’s opportunities for finding meaning in life through inspiration’), and values. A reference for values is given by generosity, moral discipline, patience, enthusiastic perseverance, and mental stability. LAKA was designed to offer covert learning and skills training for enhancing a sense of self characterized by autonomy, values, and perspective.</p>	<p>This learning content may converge with and diverge from related concepts known in published scientific literature, including:</p> <ul style="list-style-type: none"> <li>- Categories of the International Classification of Functioning: specific (higher) mental functions, and activities and participation domains 6-9.<sup>1</sup></li> <li>- Coping flexibility under conditions of CP or FSS.<sup>2</sup></li> <li>- Eudaemonist process of psychological well-being.<sup>3</sup></li> <li>- Autonomously motivated pro-social behaviour.<sup>4 5</sup></li> <li>- (Neuro) psychological processes associated with similar practices (focused attention, open monitoring, and ethical enhancement) in general: self-awareness, self-regulation, and self-transcendence.</li> </ul>
<p>Improvement in mobility of mind is associated with better health outcomes after rehabilitation in patients with complex pain or fatigue (1<sup>st</sup> and 2<sup>nd</sup>).</p>	<p>Learning content may converge with and diverge from similar plausible targets in non-pharmacological treatment for patients with CP or FSS: Internal control beliefs (+), avoidance (-), self-acceptance (+), mindfulness (+), values-based action (+), rumination (-), catastrophizing (-), negative (-) and positive mood and social interaction (+)<sup>2 6</sup></p>
<p>(Video) game mechanics can be leveraged to enhance learning through player’s self-awareness and intrinsic motivation. The game is of a relatively short duration, but promotes continued practice by any means outside the game. ‘Serious gaming sessions are planned after educational components (stress management and well-being, cognitive restructuring, and meditation) to enable complementary learning engagement and transfer’</p>	<p>Plausible ways in which video game mechanics may affect the self in players (on different levels):</p> <ul style="list-style-type: none"> <li>- Self-efficacy theory: vicarious learning in health behaviour games.<sup>7</sup></li> <li>- Self-determination theory: gaming elicits representations of valued self-identities (through autonomy, competence, and relatedness).<sup>8</sup></li> <li>- Meta-cognitive processing is a likely consequence of, and characterizes interaction in the context of video game-play.<sup>9</sup></li> <li>- Distinctive features of serious gaming strengthen (moderate) effects of behavioural change content on outcomes<sup>7</sup></li> </ul>

## 2. User interface and screenshot examples



User interface (accessibility): The human-computer interface is designed for being easy to use (i.e. there is no time pressure). It is controllable by individuals with low computer skill. It involves making decisions by tapping on the screen (pre-selecting and confirmation). One of the casual mini-games involves usage of the tilting mechanism of the tablet pc, for steering an object. Progress is never dependent on gaming skills.

### 3. Information about the design rationale, functionality, validity proof (before outcome evaluation), and data protection

Category	Item	Question	Answer
<u>Game description</u>			
Meta-data	Operating system	Operating systems of the game	Android, iOS, Windows, OS X
	Version	Version	Beta+
	Web-link	Web-link	Yes*1
	Project type	Commercial, non-commercial, other	Non-commercial
	Access	Public / restricted / other	Restricted
	Adjunct devices	Is an adjunct device needed?	No adjunct device needed
	Development	Funding	How was development funded? Eg, funding agencies, investors
Sponsoring / Advertising	Advertisement policy	Is the game free of commercial pop-ups?	Yes
		If not, what is advertised?	NA
	Sources of income	Are there sources of income within the game?	No
	Sources of income outside game	What are the sources of income of the owner/distributor?	The owner and distributor (Ciran) is a foundation providing outpatient rehabilitation care covered by health insurance.
Potential conflicts of interest	Affiliations	What affiliations do the publishers have that could influence content or user group?	Publishers are affiliated with the owner/distributor
	Conflicts of interest	What interests do the publishers have that could influence the game's content or user group?	Content and user groups are based on the objective of Ciran to improve outpatient rehabilitation for patients with complex chronic pain and/or fatigue. The primary (tentative) purpose of game design is the improvement of (independent) engagement with learning content during a rehabilitation program.
	Disclosure	Are conflicts of interest disclosed?	Yes
<u>Rationale</u>			
Purpose	Goal or purpose	What is (are) the purpose(s) of the game?	To facilitate learning and promote practice for 'mobility of mind' (see developer assumptions) to support recovery in patients with complex chronic pain and/or fatigue.
	Disclosure	Is (are) the purpose(s) disclosed to users?	Yes
Medical device	Medical device	Is the serious game a medical device, or not?	Not
	Class	If yes, which class?	NA
	Approval by legal bodies	If yes, does it comply with the necessary requirements (FDA-approval, CE-mark?).	NA
User group	Specific user groups	For each user group: disease/condition	Patients with chronic pain and fatigue, and problems in multiple (other) domains of functioning.

	Description	Please specify gender, age (range), and other relevant descriptive items.	See inclusion and exclusion criteria as listed in the main body of the article.
	Limits	Are there age limits, or other limits?	According to PEGI classification, the content of the game was found suitable for people who are at least 12 years of age, because it contains some events of mild swearing.
	Disclosure	Is the intended user group disclosed?	Yes
Setting	Patient care	Is the game used in patient care?	Yes
	Training courses	Is the game used in training courses or - curricula?	No
	SCORM compliancy	If used in training courses or curricula, is the serious game SCORM-compliant?	NA
<u>Functionality</u>			
Purposes / didactic features	For every purpose of the game:		
	Learning or behavioural goals	What content will the player learn?	Learning content is based on a reference set of values that manifest in (pro-social) thought and behaviour. These values correspond with the 'perfections' of Mahayana Buddhism. Learning this content is, for research purposes, interpreted as a process of psychological well-being through self-awareness, self-regulation, and self-transcendence (see developer assumptions).
	Relation learning and game play	How does the learning content relate to the game play?	<p>Players are supported in imagining how valued states (or 'selves') are attainable when going on a trip around the world (as a metaphor for private, social, or work participation). Before the game starts, players are explicitly instructed to identify with an Avatar (of their chosen gender and name). It is stated that Avatar choices reflect you as a player. In an introductory cut-scene, this Avatar meets a non-playing character (NPC), named LAKA. The personal Avatar is introduced as someone who experienced deterioration in physical and social domains of functioning, and is determined to improve his/her life. Then, LAKA challenges the Avatar 'to cope well with others' on a trip to 4 destinations (London, Turkey, Asia, and Africa). Meanwhile, most of the mechanics of LAKA enable (virtual) exploration and affirmation of values by selecting action plans for the personal Avatar. At each travel destination, the Avatar faces 4 encounters with NPC's under various circumstances. These encounters are designed as complex interactions between Avatar actions and unpredictable responses of the NPC/environment (rendering variety in cultural settings). For each Avatar action, players select an action plan out of 5 programmed options for physical acting, saying, and/or avoiding. The action plans are modelled by their level of correspondence with values for a given situation.</p> <p>After visiting a destination (after 4 encounters), LAKA appears and asks the Avatar to provide a self-rating of his/her performance, provides feedback on chosen action plans (by giving a certain number of puzzle pieces), and feeds back how well Avatar</p>

			<p>self-ratings and LAKA ratings correspond (by providing additional puzzle pieces). Finally, LAKA delivers focused attention and open monitoring exercises (explaining and illustrating how to practice meditation, prompting practice, providing a means for stress management).</p> <p>Learning elements are interspersed with short (casual) action and puzzle games, images, and information associated with the location of the Avatar. These features promote enjoyment by varying game play and rewarding curiosity, and can be skipped if preferred.</p>
	Instruction	What intervention leads to the learning transition (eg, tutorial, instructions (in-game))	Besides prompting identification with the Avatar, and adding feedback by LAKA as a form of in-game debriefing, face-to-face debriefings by care providers are offered to improve the transition from game play to learning for daily life improvements.
	Assessment (progress) in game	Through which parameters is progress in the game measured?	Number of encounters completed (progress does not depend on player learning level), but feedback is provided on actions chosen by players.
	Assessment parameters	Which parameters are to designers' opinion indicative for measuring learning effects?	Primary health outcomes (i.e. pain, fatigue) may be an indirect result of learning. Parameters that may indicate a learning effect more directly may be plausible mediators of outcome improvement after behavioural interventions in CP or FSS patients (see developer assumptions). Parameters of game play may also directly reflect learning effects: 1) LAKA assessments may reflect whether a patient thinks and acts in accordance with values, 2) the level of correspondence between self-assessment and LAKA assessment may contain information about the extent to which the player understands what sort of thinking and behaviour relates to psychological well-being.
Content Management	Content Management system	Is the Content Management System restricted to specified persons or institutions?	Yes
	User uploaded content	If no, are users allowed to upload their own content?	NA
	Content monitoring	How is uploaded content checked?	NA
	Restrictions and limits of the serious game	Please describe restrictions and limits of the serious game. What content on the learning goals is not covered?	<p>The game itself does not contain detailed explicit knowledge on relationships between learning content and health outcomes. Complementary delivery modes of rehabilitation (i.e. handbooks, group therapy sessions) serve this purpose. An argument for withholding highly explicit feedback is that the adequacy of action plans (coping) is context dependent. The game enables safe exploration of options for (non-automatic) responding to contextual clues. Consequently, the game triggers reflection by leaving some ambiguity about what might be the 'right' sort of behaviour.</p> <p>This ambiguity might diminish levels of acceptance/playability (perceptions on feedback or challenge) in some players. Professional support may partially compensate this issue when embedding the game within regular treatment. The game was found to be engaging enough to play ones or twice (2-5 hours), which is</p>

			not expected to be enough for moderate or strong average effects on player behaviour and health outcomes.
Potentially undesirable effects	Potentially undesirable effects	What potential undesirable effects could the game have?	No undesirable effects were expected and none were observed in qualitative analysis during a feasibility study* <sup>3</sup> .
	Disclosure	Are such potential undesirable effects disclosed to the user?	NA
	Measures taken	What measures are taken to prevent potential undesirable effects?	Based on the result of feasibility study, we expect no undesirable effects. During the present evaluations, undesirable effects will be investigated again.
<u>Validity</u>			
Design process	Medical expert complicity	Were medical experts (content experts) involved in the design process from the start?	Lama's from the Tibetan Institute Yeunten Ling, a psychometric expert; A.H. Akkerman, and Ciran; A.H.M.M. van Bergen, and J.J. Jochijms created the 'mobility of mind' questionnaire that operationalizes the content on which LAKA is based. They were also involved in the formulation of program requirements, or provided feedback on prototypes of LAKA.
	User group complicity	Were representatives from the user group involved in the design process from the start?	No
	Educationalist complicity	Were educationalists involved in the design process from the start?	Educationalists have been affiliated with Tilburg University: Prof. Jac L.A. Geurts (gaming expert) had been guiding the process of demand specifications for LAKA. M.A.P. Vugts MSc has been involved as a researcher from the start.
User testing	User testing	Did user testing take place? What were the results, and how were these incorporated in the design?	User testing was performed in feasibility piloting* <sup>3</sup> . The game is free of technical issues. Some comments on playability have not been addressed, because their impacts on outcomes are ambiguous. The only change to the version used in the feasibility study is that mini-games can be skipped after one failed attempt (instead of 3) to increase tailoring to user preferences.
Stability	Platform stability	Does the game produce the same results on different platforms?	Yes
Validity (effectiveness)	Face validity	Do educators and trainees view it as a valid way of instruction?	Yes. Educators agree that learning content is integrated in a valid way (according to the creators of the Mobility of Mind model (see 'content validity'), and agree that its content corresponds with processes of mental well-being as described by the S-ART model (MV, AZ). A group of self-selected patient users recognize that learning content correspond to what is learned by other means (from psychotherapists) during the rehabilitation program* <sup>3</sup>

	Content validity	How is its content validated to be complete, correct, and nothing but the intended medical construct?	A structured self-report questionnaire to assess thought and behaviour in correspondence with values as defined in the teaching model of the 6 perfections was created by Ciran in collaboration with the Yeunten Ling institute (Belgium). A validation report on this test was assessed by an independent Dutch commission for test affairs (COTAN). It was found that questionnaire scores have good reliability, and are strongly correlated with psychological well-being (as expected). Game scenarios were constructed by a professional writer who was familiar with the model and made explicit references to questionnaire items within screen plays for content validity checks. The quality of scenario's and operationalization was monitored under supervision of a creator of the test.
	Construct validity	Is the game able to measure differences in skills it intends to measure?	Research in progress
	Concurrent validity	How does learning outcome compare to other methods assessing the same medical construct?	Concurrent validity was studied using unreported data that were collected in the pilot phase (n=67 patients). A preliminary measure of game score was calculated as the average of all chosen action plans (the quality of each action plan is scaled ordinal; 0, 1, 2, 3, or 4). Performance was assessed by summing the scores for 5 scales corresponding with the behavioural domains of the values questionnaire (generosity, moral discipline, patience, enthusiastic perseverance, and mental stability). Pearson correlations between game scores and the behavioural domain of the values questionnaire were found to be significant, and of a small to moderate size. Self-assessed values measured at baseline (measured within a month before playing the game) correlated .29 with game scores. Values measured post-intervention (1-2 months after playing the game) correlated .39 with game scores. This agreement is encouraging given the differences in how to construct indicators were measured.
	Predictive validity	Does playing the game predict skills improvement in real life?	Research in progress
<u>Data protection</u>			
Data protection and privacy	Data processing	How is data collected in the serious game?	The game can only be accessed by clients of Ciran by logging in with their treatment ID number and self-chosen password. Log-data are encrypted, send over the internet, and stored by Ciran to save proceedings and enable feedback of game scores. No patient-specific data are stored on devices.
	Patient privacy	Are patient-specific data stored in the game?	Data are recorded by Ciran includes IP addresses, name given to the Avatar (no name, or alias is possible), which could be used to identify users.

		If yes, are patient informed consent criteria met according to relevant national standards?	Yes. All clients at Ciran are informed before the start of their treatment about the use of a digital tracking system for creating and maintaining a patient record, and about their rights for managing their personal records. Therefore, game data concern progress of the treatment and can only be used for scientific research under strict conditions. Therefore, a research protocol describing the codified processing of log-data (thus not including potentially patient specific IP addresses and Avatar names) for the evaluation of LAKA was approved by the ethical committee of Tilburg School of Social and Behavioural Sciences. Medical ethics review is not required for the research.
	Data ownership	Who owns and stores the data resulting from play?	Ciran
	Data storage period	During what period are data stored?	In accordance with the legal storage of medical records (15 years)
	Data removal	Can the user delete data temporarily and/or permanently?	Yes
	Data storage security	Is the data storage secured in conformity with laws of the countries stated above?	Yes
	Data transmission security	Is the data transmission secured in conformity with laws of the countries stated above?	Yes
	Disclosure	Are all items on "data protection" disclosed to the user?	Yes. All items are disclosed to patients before starting their treatment. Specific information on the storage of game data for progress tracking and feedback have not been highlighted in the consent procedure.

\*1 Prototype trailer (English): <http://www.ciran.nl/laka/lakaEnglish.php>; Trailer of the experimental version of the game (Dutch): <http://www.ciran.nl/laka/lakaNed.php>

\*2 <https://www.ciran.nl/>

\*3 Vugts MA, Joosen MC, van Bergen AH, et al. Feasibility of Applied Gaming During Interdisciplinary Rehabilitation for Patients With Complex Chronic Pain and Fatigue Complaints: A Mixed-Methods Study. *JMIR serious games* 2016;**4**(1).

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