TECHNOLOGY VERIFICATION REPORT

NAME OF THE DEVICE:	Phototherapy panel
AUTHORS OF THE REPORT:	PhDr. Jana Kopřivová, Ph.D.[1]
	Ing. arch. Lenka Maierová, Ph.D.[2]
	M.Sc. Kateřina Červená, Ph.D.[1]
	Ing. arch. Hana Kárníková [2]
	doc. RNDr. Zdeňka Bendová, Ph.D.[1]
VERIFICATION WORKPLACE:	[1]National Institute of Mental Health
	[2]University Center for Energy Efficient Buildings CTU
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DESCRIPTION OF THE DEVICE

The phototherapy panel is a portable light fixture the size of cabin baggage. It is designed to be placed on a table so that its illuminated surface is at eye level of the sitting person. It is designed to ensure support for clients during their transition from clinical care to everyday life. The light output of the luminaire reaches a distance of 50 cm from the light-changing surface at a photopic illuminance of 3000 lx, equal to a melanopic daytime illuminance of D65 (mEDI) of 2800 lx.

The appropriate timing of the therapy can be preset in the control system, thereby adapting the light fixture to the client's individual needs. Online connection and data sharing is enabled, giving the attending physician or other qualified staff real-time access to information about the progress of the client's therapy.

Object of verifying the technology

The object was to verify whether the technology of the phototherapy panel affects subjective experience and physiological variables, and whether it is feasible to use it at home while simultaneously monitoring the cooperation of the subjects.

PROCEDURE FOR VERIFYING THE TECHNOLOGY

Verification studies of the phototherapy panel technology took place in the conditions of everyday life, outside of clinical facilities, on healthy subjects with increased sensitivity to seasonal changes. The subjects did not work in shift work at the time of the study and did not use sleep medication.

Study participants were monitored for six weeks using an actigraph, which records movement activity, and kept a diary every day in a mobile application paired with the actigraph. They also used a mobile application to map their current psychological state every evening. Light exposure using the photoherapy panel took place in the second two-week study. At the beginning of the study and on the last day of exposure to light from the phototherapy panel, the participants completed a set of questionnaires to assess the quality of their sleep and mood.

Verification was performed in the following areas:

- Affective experience and mood
- Sleep
- Circadian rhythms
- Monitoring cooperation of the subject

Influence on affective experience and mood

Two-week regular exposure to light from the phototherapy panel (approximately 3000 lx) led to a significant reduction in subjectively experienced symptoms of depression according to a standardized BDI (Beck Depression Inventory) self-assessment questionnaire. The results of the Short Self-Assessment Scale focused on the daily monitoring of the psychological state of the subjects show that they felt better in the period after the end of the phototherapy compared to the initial measurement.

Effect on sleep

The results of the statistical comparison show a significant improvement in subjectively assessed sleep quality according to the PSQJ (Pittsburgh Sleep Quality Index) after two weeks of regular light exposure from the phototherapy panel. An analysis of the data from the sleep diaries shows that the probands fell asleep faster during phototherapy, i.e. subjective sleep latency decreased significantly during phototherapy and the time it took to

fall asleep did not increase after it stopped

Effect on circadian rhythms

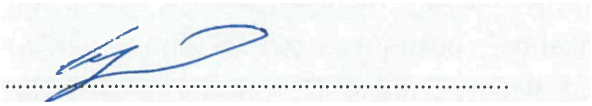
An analysis of the actigraphic records shows the study participants had an earlier acrophase of the circadian rhythm of physical activity during the period of phototherapy than during the period monitored at the beginning of the study. They also had a slightly, though not significant, shift in their mean sleep time. The inter-day stability of the circadian rhythm of physical activity did not change during phototherapy. It can therefore be summarized that regular exposure to light from the phototherapy panel in the home environment leads to a shift in the phase of the circadian rhythm, in such a way that the acrophase of the rhythm of physical activity shifts to earlier hours. This phase advance and its correlation with the phase of mean sleep time indicate a shortening of the internal period of the participants' circadian clocks and an improvement in their synchronization with social time.

Verification of the system for monitoring the cooperation of the proband

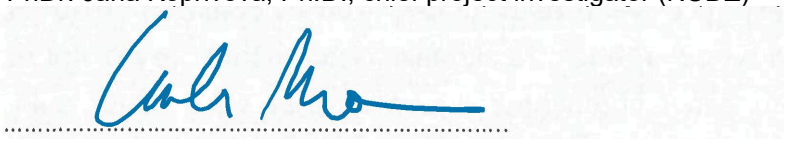
Considering that the light exposure took place in a home environment, where the time of its actual use could not be controlled by professional staff, a possible time-window for light exposure was individually preset in the phototherapy panel device for each individual. This eliminated the risk of possibly turning on the phototherapy panel at an inappropriate time (e.g. in the evening). At the same time, a cooperation monitoring system was set up in this verification study, where the proband was required to press the presence button every 5-12 minutes (otherwise the phototherapy panel would turn off). Data on when the device was in operation and data on whether the patient responded by pressing the button to change the light intensity was wirelessly sent to a remote storage location, where it was continuously monitored by an experimenter. An example of remote communication can be found in Annex 1.

DETAILED REPORTS AND RESULTS OF VERIFICATION EXPERIMENTS See Annex 1.

In Klecany, 31 December 2023



PhDr. Jana Kopřivová, Ph.D., chief project investigator (NUDZ)



Ing. arch. Lenka Maierová, Ph.D., chief project investigator (UCEEB, CTU)

PhDr. Petr Winkler, Ph.D., representative of the originating organization (NUDZ)

Ing. Robert Jára, Ph.D., representative of the originating organization (UCEEB, CTU)

Daniel Jesenský Ph.D., MSc., MBA, for users of the verified technology