Pilot Testing of a Computer-Aided Prevention System (CAPSYS)
Study Protocol of a Randomized Controlled Trial

Lübomira Spassova[1], Norbert Rösch[2], Debora Vittore[3] and Dirk W. Droste[3]
[1]*Public Research Centre Henri Tudor, SANTEC, 29, avenue John F. Kennedy, 1855, Luxembourg, Luxembourg*
[2]*University of Applied Sciences Kaiserslautern, Amerikastr. 1, 66482, Zweibrücken, Germany*
[3]*Centre Hospitalier de Luxembourg, Department of Neurology, 4, rue Ernest Barblé, 1210, Luxembourg, Luxembourg*

Keywords: Lifestyle Coaching, CVD Risk Factors, CVD Prevention, Randomized Controlled Trial.

Abstract: The CAPSYS system enables automated lifestyle coaching for CVD patients through a phone-based interface with the aim of establishing a healthy behavior by reducing specific risk factors. This paper presents the procedure of a randomized controlled trial currently performed to evaluate the CAPSYS prevention approach in terms of efficacy and usability.

1 BACKGROUND

Cerebro-cardiovascular diseases (CVDs) – especially heart disease and stroke – are the leading causes of mortality worldwide, and it is estimated that the annual mortality rate for CVDs will even increase in the coming decades (WHO, 2013). According to the WHO, unhealty diet, obesity, physical inactivity, high blood pressure and tobacco use are among the main risk factors for CVDs. Thus, to prevent heart disease and stroke, affected persons are advised to engage in regular physical activity, to avoid tobacco smoke, to achieve and maintain a normal body weight, and to stick to a healthy diet rich in fruit and vegetables, avoiding too much fat and sugar. It could be shown in several studies and epidemiologial analyses that the risk of stroke or myocardial infarction can be reduced through a healthy diet and regular physical activity (Droste, 2013).

The Computer-aided Prevention System (CAPSYS) has been developed by health scientists and IT experts in collaboration with neurologists with the aim to support patients in the primary and secondary prevention of CVDs (Spassova, 2013). This system allows patiens to provide information on their individual CVD-related risk factors through a phone-based interface. Based on this data, each patient receives system-generated customized feedback on his or her progress and advice on how to proceed reducing the risk factors that are still in a critical range. Based on recommendations by the Luxembourg Medical Scociety, this computerized processing of patient data allows automated personalised lifestyle coaching of patients in real time. The attending physician can monitor the progress of each patient through a secure web interface offering a graphical representation of the development of the corresponding risk factors (see Figure 1).

The CAPSYS lifestyle coaching approach is currently evaluated in a randomized controlled trial (RCT) in terms of efficacy in reducing the concerned risk factors as well as regarding its usability and user acceptance.

2 RELATED WORK

In a parallel two-arm RCT with 171 participants with ischemic heart disease, Maddison et al. investigated the efficiency of a mobile phone and internet-based cardiac rehabilitation program, which was delivered for six months and consisted of physical exercise prescription and behavioral change support in form of text messages sent to the participants of the intervention group (Maddison, 2011). Although no statistical difference could be observed for the primary outcome, which was peak oxygen uptake (PVO_2), significant differences were found concerning physical activity, task efficacy and motivation as well as for the general health domain of the SF-36 health-related quality of life measure in favor of the intervention group (Carter, 2013).

Spassova L., Rösch N., Vittore D. and Droste D..
Pilot Testing of a Computer-Aided Prevention System (CAPSYS) - Study Protocol of a Randomized Controlled Trial.
DOI: 10.5220/0005142800500054
In *Proceedings of the 2nd International Congress on Cardiovascular Technologies* (CARDIOTECHNIX-2014), pages 50-54
ISBN: 978-989-758-055-0

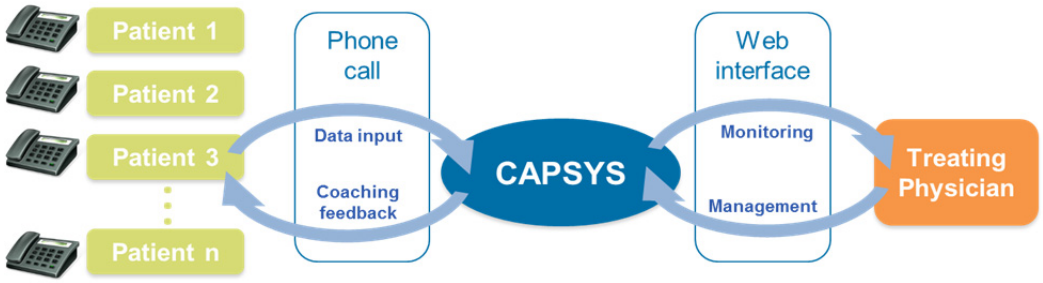

Figure 1: Architecture of the CAPSYS system.

In another study, Pfaeffli Dale et al. evaluated the efficacy of a 4-week healthy eating program in achieving behavior change among 20 CVD patients with high blood cholesterol (Pfaeffli Dale, 2014).

The modality of the intervention was very similar to the one applied in the Maddison study, i.e. text messages providing support for behavioral change received through mobile phones or through a website. However, in this case the aimed behavioural change consisted in establishing a healthy diet. The results revealed some post-intervention increase in perceived self-efficacy concerning heart-healthy eating.

Walters et al. have developed a mobile phone and web-based care model for outpatient cardiac rehabilitation, and they have evaluated this approach in a 6 week program (Walters, 2010). The system provides daily motivational messages sent through SMS and weekly mentoring by human assistants through video conferencing. These mentoring sessions involve the setting and assessment of specific goals concerning exercise and behavior modification. Some factors, such as movement activity, are automatically measured through sensors. Results show significantly higher adherence rates, larger walking distances, weight reductions and improved emotional states in the intervention group as compared to the control group (Walters, 2012).

These empirical results support the assumption that telephone-based lifestyle coaching can lead to an improvement in health behavior in the CVD context. According to the Fogg Behavior Model, human behavior is based on the presence of three fundamental factors: motivation, ability and triggers (Fogg, 2009). In the proposed CAPSYS setting, the phone-based interventions provide motivational feedback and at the same time build the triggers for positive behavior change. The ability of the users to participate in the coaching intervention is supported by the simplicity of the phone-based interface (Rösch, 2013).

3 STUDY DESIGN

The CAPSYS study has been implemented as a parallel two-arm RCT with the following criteria.

Inclusion criteria:

- Age: from 20 with no upper limit;
- Patients who already suffered a stroke or Transient Ischemic Attack (TIA);
- Patients with at least two increased risk factors for stroke:
  - High blood pressure
  - Overweight
  - Low physical activity
  - Smoking
  - Unhealthy diet

Exclusion criteria:

- Inability to fill out or to understand the informed consent;
- No signed informed consent;
- Dementia

Participants are contacted and screened for eligibility by the attending neurologist during medical consultations. After signing an informed consent, patients are randomly assigned either to the standard care group (SC) or to the interventional care group (IC). A total of 94 patients have been recruited (SC: 46, IC: 48). At the beginning and at the end of the 6-month study period, the participants from both goups are asked to complete a questionnaire on demographic and medical data, including:

- Medical history (stroke, TIA, diabetes etc.)
- Current medication
- Risk factors:
  - Smoking habits
  - Body weight, height (→ BMI)
  - Blood pressure, heart rate
  - Blood test results (HDL, LDL, HbA1c, glycemia and triglyceride levels)

In addition, three further questionnaires are to be completed also at the beginning and at the end of the

study period to collect data about the nutritional habits, the physical activity and the quality of life of the participants from both groups.

With the questionnaire on nutritional habits, participants can self-assess their usual daily or weekly food consumption at baseline and post-intervention. The questionnaire encompasses a number of food groups such as fish, meat, dairy, fruits, vegetables, sweets, alcohol etc.

The questionnaire on physical activity asks for a self-assessment of the following types of activity (in hours and minutes) that the participants usually perform per week:

- Low intensity: normal breathing, no sweating
- Moderate intensity: slightly accelerated breathing, potentially some sweating
- High intensity: rapid breathing and sweating

Finally, information about the participants' quality of life is acquired by means of the standardized EQ-5D-5L instrument provided by the EuroQol Group (The EuroQol Group, 1990).

At the beginning of the study, the participants are assisted by an interviewer (a study nurse, an assistant doctor or the project staff) in filling in the questionnaires. The blood pressure and the heart rate of each participant are measured by the interviewer at the beginning and at the end of the study period. Data concerning the participants' medical history, current medication and blood test results are taken from the corresponding medical files. At the end of the recruitment meeting, patients of both groups are handed out a leaflet with information on healthy lifestyle, especially concerning nutrition and physical activity as guidance for reducing their risk factors.

Patients in the IC group are assigned a personal account (patient number and PIN code) for accessing the CAPSYS system. The interviewer demonstrates how to use the CAPSYS system and provides a paper-based user guide with detailed instructions on the application. The IC participants are advised to call the CAPSYS system twice a week (preferably on Mondays and Thursdays).

During the study period, SC participants do not undergo any special treatment, but they receive the usual care by their treating physicians. In addition to the usual medical care, IC participants are provided the possibility to use the CAPSYS system in order to provide information about their current lifestyle concerning certain CVD risk factors and to receive feedback on the provided values by the system (see Figure 2). The participants can access the system by calling a land line number with their stationary or mobile phones. After they have chosen their preferred language (French or German) and authenticated themselves with their patient number and PIN code, the participants are posed some automatically generated questions concerning their current blood pressure and body weight, and about their physical activity and their consumption of fruits, vegetables, whole-grain food and sweets on the previous day. For smokers, cigarette consumption is also considered.

During the recruitment meeting at the beginning of the study, participants are instructed on how to estimate portion sizes for the relevant food groups, and they are advised to measure their current blood pressure and body weight, and to write down all necessary values prior to calling the CAPSYS system. The system is implemented to run fully automatically and can be accessed at any time of day. The questions and feedback generated by CAPSYS are issued to the users in spoken natural language by means of text-to-speech software (TTS). The participants can answer to the questions by typing in corresponding numerical values using the phone key pad (e.g. "3" for 3 portions of fruits

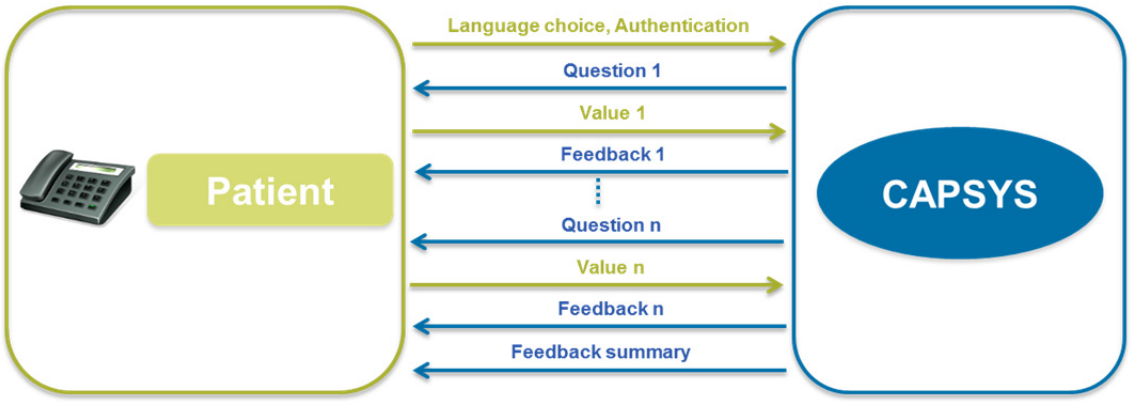

Figure 2: Outline of a CAPSYS phone call.

and vegetables, or "79" for a body weight of 79 kg). All provided values are automatically saved in a secure database for later evaluation.

At the end of their study participation (approx. one month before the end), participants are contacted by letter requesting them to fill in the final questionnaires as far as possible (except for medical data) and to bring them to their next appointment with the attending neurologist. If participants need support in completing the finalization questionnaires, they are supported by an interviewer, who also measures their blood pressure and heart rate and fills in the required medical data. In addition to the finalization questionnaires, which are almost identical to the ones completed at the beginning of the study (nutrition, physical activity and quality of life), IC participants are asked to fill in one additional form with questions concerning the usability of the system and the user satisfaction. This questionnaire encompasses the standardized System Usability Scale (SUS) (Brooke, 1996) and a number of system-specific questions, e.g. concerning the system features (quality of the TTS voice, adequacy of the automated feedback etc.), the preferred frequency of use and the perceived benefits after 6 months of usage.

Taking into account the bilingual setting of the study site, all questionnaires as well as the CAPSYS system itself are available in French and German.

Both at the beginning and at the end of the study, data are collected through paper questionnaires and saved in electronic form in a dedicated secure database.

The CAPSYS study has been approved by the Luxembourg National Research Ethics Committee (CNER) (N° 201205/08) and the National Commission for Data Protection (CNPD) (T007990).

4 EVALUATION APPROACH

The main objective of the CAPSYS study is the evaluation of measurable clinical effects of computer-supported lifestyle coaching in patients with increased CVD risk factors. Consequently, the primary endpoint of the study is the change of CVD risk factors over time in both study arms.

Questionnaire data (q-data) and measurements (m-data) of physiological parameters (blood pressure, BMI, HDL, LDL, HbA1c and glycemia) are collected at baseline and post-intervention. Individual risk profiles and patterns of patients will be generated and analyzed based on official recommendations by the EACPR (European Association of Cardiovascular Prevention and Rehabilitation) (Perk, 2012). Data will be analyzed using the Student's t-test approach (Hazewinkel, 2001). Paired t-tests will be applied to find significant changes in the physiological parameters between baseline and post-intervention. Unpaired two-sample t-tests for each parameter can reveal possible significant differences in increase or decrease of risk factors between the two groups. Statistical analyses will be performed using the R environment, with a significance level of 0.05.

As secondary endpoint, health-related quality of life (HR-QoL) will be analyzed. The quality of life data collected through the standardized EQ-5D-5L questionnaire (health profiles and values of the EQ visual analogue scale (EQ VAS)) will be summarized in appropriate charts according to the EuroQol guidelines.

The usability of the CAPSYS system will be evaluated based on the results of the SUS form (standardized numeric evaluation schema) and the answers to the additional system-specific questions provided by the IC participants.

5 CONCLUSIONS

The study presented in this article aims at evaluating the efficacy and usability of the CAPSYS approach for phone-based lifestyle coaching of CVD patients concerning risk factor reduction. The results of this study will be presented in a separate publication upon study finalization. In case the results provide proof of clinical impact, the health economic aspects of the proposed approach will need to be further investigated. Potential implementation and maintenance costs concerning the incorporation of CAPSYS into CVD healthcare will be analyzed and compared to those of traditional and alternative CVD prevention approaches. Based on the usability evaluation results, the CAPSYS system will be further refined and adapted to the users' needs.

REFERENCES

WHO, *Cardiovascular diseases (CVDs)*, Fact sheet No. 317, World Health Organization, 2013

Droste, D.W., Keipes, M., 2013. (The reduction of stroke risk, risk of myocardial infarction and death by healthy diet and physical activity.) In *Bulletin de la Societe des Sciences Medicales du Grand-Duche de Luxembourg*, 2013(2):51-62.

Spassova, L., Rösch, N., Vittore, D., Droste, D.W., 2013. CAPSYS: Computer-aided Prevention through Automated Lifestyle Coaching. In *Proceedings of IADIS International Conference on e-Health*, pp. 169–173.

Spassova, L., Vittore, D., Droste, D., Rösch, N., 2013. Automated lifestyle coaching for cerebro-cardiovascular disease prevention. In *Studies in Health Technology and Informatics*, vol. 190, pp. 234–236.

Maddison, R., Whittaker, R., Stewart, R., Kerr, A., Jiang, Y., Kira, G., Carter, K.H., Pfaeffli, L., 2011. HEART: heart exercise and remote technologies: A randomized controlled trial study protocol. In *BMC Cardiovascular Disorders 2011*, 11:26

Carter, K., Maddison, R., Whittaker, R., Stewart, R., Kerr, A., Jiang, Y., Pfaeffli, L., Rawstorn, J., 2013. Heart: Efficacy of a mHealth Exercise-based Cardiac Rehabilitation Program. In *Heart, Lung and Circulation*, 07/2013, 22(7):553.

Pfaeffli Dale, L., Whittaker, R., Eyles, H., Ni Mhurchu, C., Ball, K., Smith, N., Maddison, R., 2014. Cardiovascular Disease Self-Management: Pilot Testing of an mHealth Healthy Eating Program. In *Journal of Personalized Medicine*, 19 March 2012, 4(1), 88-101.

Walters, D.L. et al., 2010. A mobile phone-based care model for outpatient cardiac rehabilitation: the care assessment platform (CAP). In *BMC Cardiovascular Disorders* 2010, 10:5.

Walters, D.L. et al., 2012. Technology Based Home-Care Model Improves Outcomes Of Uptake, Adherence And Health In Cardiac Rehabilitation. In *Heart, Lung and Circulation* 2012, 21:S143–S316.

Fogg, B.J., 2009. A Behavior Model for Persuasive Design. In *Proceedings of the 4th International Conference on Persuasive Technology*, 40:1-7.

Rösch, N., Spassova, L., Vittore, D., Droste, D.W. , 2013. (Computer-aided Lifestyle Coaching complements telemedical control of cerebro-cardiovascular risk factors). In *Nutzung, Nutzer, Nutzen von Telematik in der Gesundheitsversorgung – eine Standort-bestimmung*, pp. 37–43, 2013

The EuroQol Group, 1990. *EuroQol – a new facility for the measurement of health-related quality of life*. Health Policy 16(3):199–208.

Brooke, J., 1996. SUS: a "quick and dirty" usability scale. In P. W. Jordan, B. Thomas, B. A. Weerdmeester, and A. L. McClelland. *Usability Evaluation in Industry*. London: Taylor and Francis.

Perk, J. et al., 2012. European Guidelines on cardiovascular disease prevention in clinical practice (version 2012). In *European Heart Journal* (2012) 33, 1635–1701.

Hazewinkel, M., 2001. Student test, *Encyclopedia of Mathematics*, Springer, ISBN 978-1-55608-010-4.