

# BMJ Open Proactive automatised lifestyle intervention (PAL) in general hospital patients: study protocol of a single-group trial

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**To cite:** Freyer-Adam J, Krolo F, Tiede A, *et al*. Proactive automatised lifestyle intervention (PAL) in general hospital patients: study protocol of a single-group trial. *BMJ Open* 2022;**12**:e065136. doi:10.1136/bmjopen-2022-065136

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2022-065136>).

Received 31 May 2022  
Accepted 11 August 2022



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## ABSTRACT

**Introduction** The co-occurrence of health risk behaviours (HRBs, ie, tobacco smoking, at-risk alcohol use, insufficient physical activity and unhealthy diet) increases the risks of cancer, other chronic diseases and mortality more than additively; and applies to more than half of adult general populations. However, preventive measures that target all four HRBs and that reach the majority of the target populations, particularly those persons most in need and hard to reach are scarce. Electronic interventions may help to efficiently address multiple HRBs in healthcare patients. The aim is to investigate the acceptance of a proactive and brief electronic multiple behaviour change intervention among general hospital patients with regard to reach, retention, equity in reach and retention, satisfaction and changes in behaviour change motivation, HRBs and health.

**Methods and analysis** A pre–post intervention study with four time points is conducted at a general hospital in Germany. All patients, aged 18–64 years, admitted to participating wards of five medical departments (internal medicine A and B, general surgery, trauma surgery, ear, nose and throat medicine) are systematically approached and invited to participate. Based on behaviour change theory and individual HRB profile, 175 participants receive individualised and motivation-enhancing computer-generated feedback at months 0, 1 and 3. Intervention reach and retention are determined by the proportion of participants among eligible patients and of participants who continue participation, respectively. Equity in reach and retention are measured with regard to school education and other sociodemographics. To investigate satisfaction with the intervention and subsequent changes, a 6-month follow-up is conducted. Descriptive statistics, multivariate regressions and latent growth modelling are applied.

**Ethics and dissemination** The local ethics commission and data safety appointee approved the study procedures. Results will be disseminated via publication in international scientific journals and presentations on scientific conferences.

**Trial registration number** NCT05365269.

## INTRODUCTION

The co-occurrence of health risk behaviours (HRBs) such as tobacco smoking, at-risk alcohol use, insufficient physical activity and/ or unhealthy diet increases the risks of

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The behaviour change intervention to be tested targets on the great co-occurrence of health risk behaviours in general hospital patients.
- ⇒ The proactive computer-based intervention is designed to reach and retain the majority of patients.
- ⇒ The theory-based intervention provides highly individualised, motivation-enhancing feedback over multiple time points.
- ⇒ Established measures are used to assess health risk behaviours and motivational aspects.
- ⇒ The study is not designed to investigate the efficacy or effectiveness of the intervention.

cancer, other chronic diseases and mortality more than additively.<sup>1 2</sup> What is more, more than half of the adult population practise two or more of these HRBs.<sup>3–6</sup> To reduce chronic diseases on the population level, individual prevention measures are recommended, particularly in healthcare settings.<sup>7–9</sup>

However, there are three major issues: First, the implementation of individual behaviour change interventions into routine healthcare is lacking. Lack of time, high work load and self-perceived lack of expertise in medical staff have been identified as barriers on the provider side.<sup>10</sup> Second, behaviour change interventions often focus on single HRBs.<sup>11</sup> Given that for example, 93% of the general hospital patients identified with at-risk alcohol use practice at least one other of the four HRBs,<sup>12</sup> neglecting the co-occurrence of multiple HRBs in persons results in missed opportunities and cost-inefficiency. Third, the ‘reach’ dimension of the public health impact of interventions<sup>13 14</sup> has been largely disregarded. That is, individual interventions often fail to reach the majority of the target population, and particularly those subgroups most in need and often hard to reach for preventive measures such as persons with low

socioeconomic status.<sup>15 16</sup> For example, persons with low level of school education do not only practice increased numbers of HRBs,<sup>17 18</sup> but are also particularly hard to reach.<sup>16</sup> The failure to reach this subgroup may further widen social inequity in health and mortality, a major and yet increasing issue in public health.<sup>19–21</sup> Thus, in terms of the public health impact,<sup>14</sup> the development of high-reach interventions that address multiple HRBs and that have a good chance to be adopted, implemented and maintained in healthcare are a major challenge for population-wide prevention of cancer and other chronic diseases.

In terms of adoption, implementation and maintenance of interventions in healthcare, digital behaviour change interventions may provide the means to relief healthcare personnel, and to store and recall intervention information reliably. In terms of reach, however, standalone applications such as web-based interventions fail to reach the majority of the target population. Although, potentially, accessible to everyone, they require the target population to seek for help, which does not apply to the vast majority of target populations, also due to little motivation to change HRBs.<sup>22 23</sup> Interventions that aim to reach the whole target population with little selectivity need to be proactive and to provide helpful intervention strategies for the large part of persons with initially low motivation to change.<sup>24 25</sup> Personalised cancer risk information derived from the number of HRBs, alone appears to be sufficient to change HRBs.<sup>26</sup> The transtheoretical model of intentional behaviour change (TTM) provides a potential theoretical background on how to address behaviour change, particularly on how to enhance motivation in persons not yet ready to change certain behaviours.<sup>27</sup> With regards to decreasing alcohol use, tobacco smoking and improving measures of health, TTM-based interventions targeting single behaviours have been found to produce desirable changes over 2 years in healthcare patients.<sup>28–31</sup>

General hospitals may provide an ideal setting to approach patients for the delivery of comprehensive lifestyle interventions for several reasons: First, two-thirds of general hospital patients report multiple of the four HRBs.<sup>12</sup> Second, with participation rates of 80% and higher, general hospital patients have been found to be reached well for individual interventions targeting single behaviours.<sup>32</sup> And third, within one single approach, a proactive automatised lifestyle intervention (PAL) could serve primary as well secondary prevention purposes among general hospital patients.

The purpose of this study protocol (30 May 2022; version 1) is to describe a study that intends to investigate the acceptance of a PAL among general hospital patients regardless of their current disease or injury. The intervention is designed (1) to address all four HRBs, (2) to reach the vast majority of the target population, also ‘most in need and hard to reach’ subgroups and (3) to produce long-term improvements concerning HRBs and health by applying psychological health behaviour change theory, by tailoring feedback to participant’s level of motivation

to change and by providing multiple feedbacks. This protocol describes a study which aims to investigate (1) intervention reach (ie, the proportion of all eligible general hospital patients who participate), (2) intervention retention (ie, the proportion of all participants who continue participation after hospitalisation), (3) equity in reach and retention for example, with regards to socioeconomic status, (4) satisfaction with the intervention and (5) trajectories of change with regards to motivation, HRBs and health-related measures over 6 months.

## METHODS AND ANALYSIS

### Study design

The single-group-intervention study, as summarised in [table 1](#), is part of a broader research project ‘PAL for cancer prevention’ funded between 1 July 2020 and 31 December 2022. The project also included the preceding development of the intervention and the conduction of a survey among general hospital patients for purposes of intervention development (PAL-Survey). This current study (also: PAL-Pilot) includes three intervention time-points at baseline, month 1, month 3 and a 6-month follow-up ([figure 1](#)). Recruitment and study procedure were tested on 3 days between 24 May 2022 and 27 May 2022. Enrolment of the first real participant started on 31 May 2022 and was completed with the last participant recruited on 5 July 2022.

### Patient and public involvement

Patient involvement includes the assessment of patient satisfaction and discomfort with the intervention. However, beyond that, patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

### Recruitment

All consecutively admitted patients aged 18–64 years from participating wards of five medical departments (internal medicine A and B, surgical medicine, trauma medicine, ear, nose and throat) at the University Medicine Hospital Greifswald in northeastern Germany are eligible to participate. The hospital provides general hospital care for 600 000 people per annum. The catchment area includes the university town of Greifswald with 59000 inhabitants and surrounding communities within a radius of approximately 25 km; the extended catchment includes primarily rural communities within a radius of up to 65 km. On four weekdays each week (Tuesdays through Fridays), trained research assistants systematically approach each patient admitted on the previous day. Patients cognitively or physically incapable, with highly infectious diseases, discharged or transferred outside the study area within the first 24 hours, already asked to participate during a previous hospital stay, with insufficient language skills or employed at the conducting research institute are excluded.

**Table 1** Study information

Data category	Information
Primary registry and trial identifying no	ClinicalTrials.gov NCT05365269; any important protocol modifications will be communicated here
Date of registration in primary registry	5 May, 2022
Secondary identifying numbers	D850000001
Source(s) of monetary or material support	Deutsche Krebshilfe (German Cancer Aid) University Medicine Greifswald
Primary sponsor	University Medicine Greifswald
Secondary sponsor(s)	Deutsche Krebshilfe (German Cancer Aid)
Principal investigators	JF-A, Prof. Dr.—Design, preparation of protocol, publication of study reports, trial management UJ, Prof. Dr.—Design, preparation of protocol, publication of study reports
Data management team	AT, FK, KS— Maintenance of trial IT system and data entry, data verification, data cleansing, participant flow documentation,
Contact for public queries	JF-A, Prof. Dr. (see corresponding author information) AT (see CTN record)
Contact for scientific queries	JF-A, Prof. Dr. (see corresponding author information)
Public title	Proactive automatised lifestyle intervention for cancer prevention in general hospital patients
Scientific title	Proactive automatised lifestyle intervention to prevent cancer in general hospital patients
Country of recruitment	Germany
Health condition(s) or problem(s) studied	Hospitalisation at a general hospital, irrespective of reason for admission and health risk behaviour profile
Intervention(s)	Proactive automatised lifestyle intervention consisting of computer-generated, individually tailored feedback on health risk behaviours; 3 times over 3 months
Key inclusion and exclusion criteria	Ages eligible for study: 18–64 years Sexes eligible for study: both Accepts healthy volunteers: no Inclusion criteria: General hospital patients admitted to participating wards of five medical departments (internal medicine A and B, surgical medicine, trauma medicine, ear-nose-throat-medicine) Exclusion criteria: patient cognitively or physically incapable, patient with highly infectious disease, patient discharged or transferred within the first 24 hours, patient already asked for participation during previous hospital stay, patient with insufficient language skills, patient employed at the conducting research institute, patient with neither telephone nor email

Continued

**Table 1** Continued

Data category	Information
Study type	Interventional Allocation: All patients receive intervention Intervention model: Single-group assignment Masking: non-blinded as participants are informed about the intervention prior to participation Primary purpose: prevention
Date of first enrolment	31 May 2022
Target sample size	175
Recruitment status	Completed: 5 July 2022
Date of final data collection	Anticipated: 31 March 2023
Primary outcome(s)	Intervention reach (time frame: month 0) Intervention retention (time frame: months 1, 3)
Key secondary outcomes	Satisfaction with intervention (time frame: month 6) Change in health risk behaviours, that is, physical activity, diet, alcohol use, tobacco smoking, sum of health risk behaviours (time frame: months 0, 1, 3, 6) Change in motivational measures, that is, stage of change, self-efficacy, decisional balance, processes of change (time frame: months 0, 1, 3, 6) Change in health-related measures, that is, body mass index, general health, mental health, number of sick days, non-communicable diseases, utilisation of healthcare (time frame: months 0, 6)

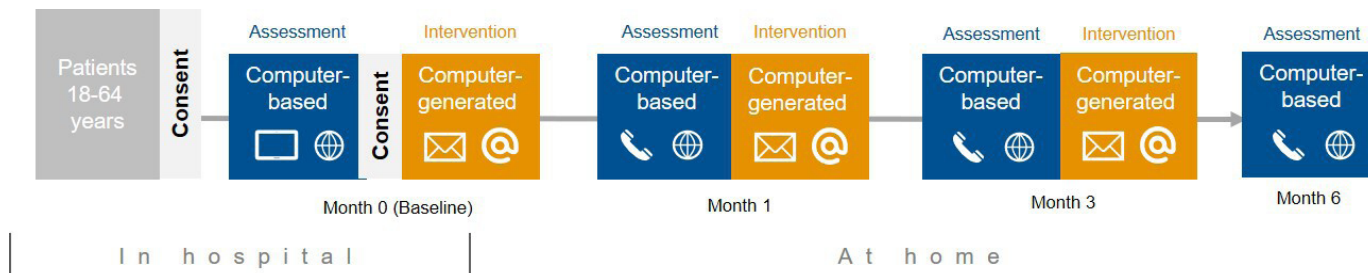
A two-step recruitment procedure is used. All eligible patients are informed about the study procedure orally and in writing, and are first asked to participate in a survey on their lifestyle. Given oral and electronic consent, the participants complete the survey using tablet PCs. After survey completion, survey participants are asked by the research assistant to participate in the intervention study. Those providing informed written consent (including usage and storage of data, see online supplemental file) then receive the intervention over three time-points, and will be followed up 6 months after baseline using computer-assisted telephone interviews (CATIs). Patients with neither telephone nor email address are excluded.

### Intervention

#### Intervention characteristics

Overall, the brief behaviour change intervention PAL is:

- ▶ Proactive: All persons of the target population are approached personally and offered to participate.
- ▶ Computer based: Feedback is generated by a computer-expert system software which generates letters that are handed out to participants (after baseline), sent to participants electronically and/or by



**Figure 1** Study design PAL. PAL, proactive automatised lifestyle intervention.

ordinary mail in case of discharge and after months 1 and 3 (figure 2).

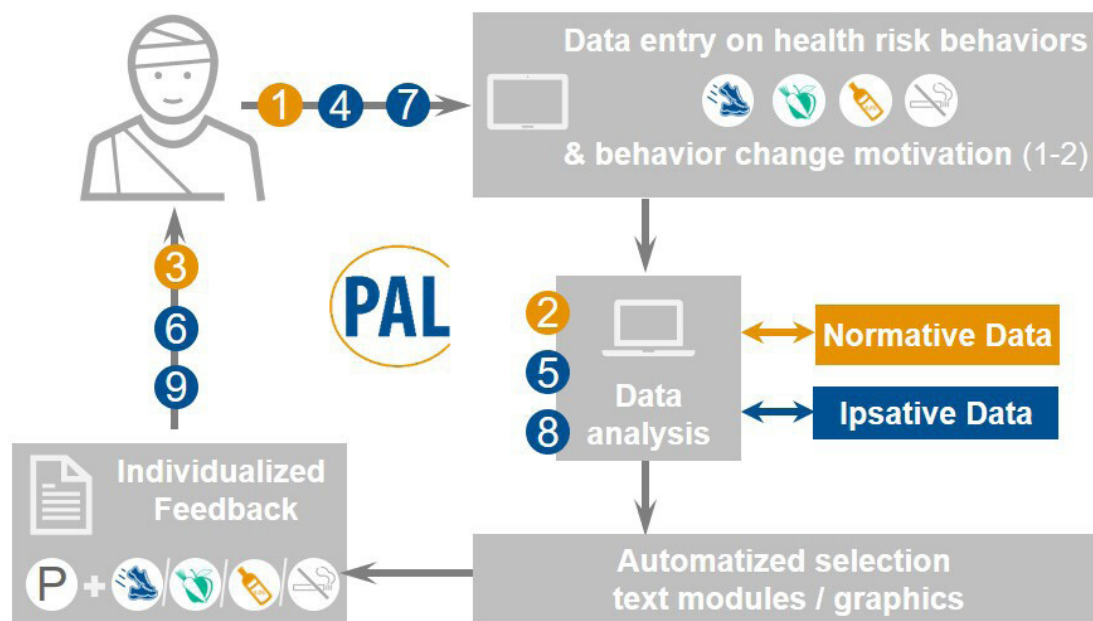
- ▶ **Multibehavioural:** The participants receive feedback on their individual HRB profile, concerning physical inactivity, unhealthy diet, at-risk alcohol use and tobacco smoking. In addition, they receive motivation-enhancing feedback for up to two HRBs.

In detail, the feedback itself is:

- ▶ **Individualised:** A pool of more than 4500 text modules, graphics and allocation rules ensures that each information fits the participant's data. Each feedback is unique, that is, no two participants receive the same feedback. For example, the smoking module alone allows the creation of 1040 to more than 442 000 unique feedbacks for smokers.<sup>33</sup>
- ▶ **Theory based:** Based on psychological behaviour change theory, and to enhance motivation to change, the participants receive feedback for up to two HRBs tailored to their current motivational stage of change according to the TTM.<sup>27</sup> While in the past, TTM-based interventions often missed the model's multidimensional nature and failed to show convincing effects,<sup>34 35</sup> interventions attending to the multiple dimensions of behaviour change theories,

and of the TTM in particular, have been shown to be related to larger intervention effects,<sup>36 37</sup> and to show over-time increasing intervention effects in healthcare populations.<sup>28-31</sup> The intervention addresses all dimensions of the TTM, that is, stage of change, decisional balance, processes of change and self-efficacy.

- ▶ **Repetitive:** Feedback is delivered three times, at baseline and 1 and 3 months later.
- ▶ **Ipsative:** Participants receive feedback on changes in their HRB profile and on changes in behaviour and motivational aspects since the last intervention time point. To do so, each intervention contact first requires computer-based assessment of HRBs and motivational aspects. The current data are then compared with the participants' previous data.
- ▶ **Normative:** Participants receive feedback on how the participant's responses compare to those of others of the same gender or in the same motivational stage. The normative data base is derived from previous studies conducted in the general population or in healthcare settings (eg, from PAL-Survey).



**Figure 2** Computer-expert system PAL. Steps 1–3 baseline, steps 4–6 month 1, steps 7–9 month 3; p=Profile of individual health risk behaviours. PAL, proactive automatised lifestyle intervention.



## Intervention modules

PAL was developed by a multidisciplinary team of psychologists, a nutritional scientist and a software engineer. As a starting point two computer-based brief interventions addressing at-risk alcohol use and smoking cessation were used as prototypes. These interventions have been shown to successfully reduce the respective HRBs and to improve measures of health in healthcare patients over 2 years.<sup>28–31</sup> These two interventions were slightly modified and integrated into the PAL intervention as two separate modules. PAL consists of five modules, that is, one HRB profile module and one module for each of the four HRBs:

- ▶ Module ‘Profile’ is delivered to all participants first. It provides information on the participant’s individual HRB profile consisting of insufficient physical activity, insufficient vegetable and fruit intake as indicator of unbalanced diet, at-risk alcohol use and tobacco smoking. Based on guidelines by the WHO, insufficient physical activity is identified when less than 150 min of moderate or less than 75 min of vigorous physical activity or less than a respective combination of both is reported.<sup>38</sup> Insufficient intake of vegetable and fruit is identified when less than five servings a day are reported.<sup>39 40</sup> According to guidelines by the German Centre of Addiction Issues<sup>41</sup> and the National Institute on Alcohol Abuse and Alcoholism,<sup>42</sup> at-risk alcohol use is identified when women/men report on average more than 1 drink (12g of pure alcohol)/2 drinks (24g) per day and/or more than 3 drinks/4 drinks per occasion. Any tobacco smoking is considered HRB.
- ▶ Module ‘Inactivity’ is delivered to participants reporting insufficient physical activity. It contains (1) behaviour feedback on the participant’s physical activity in relation to guidelines<sup>38</sup> and other women or men, and (2) motivation-enhancing feedback on increasing physical activity. [Table 2](#) includes further details.
- ▶ Module ‘Diet’ is delivered to participants reporting insufficient vegetable and fruit intake. It contains (1) behavioural feedback on the participant’s intake of fibre, fat, salt and sugar and on vegetable and fruit intake according to recommendations by the WHO and the World Cancer Research Fund,<sup>39 40 43–45</sup> and (2) motivation-enhancing feedback on increasing vegetable and fruit intake.
- ▶ Module ‘Alcohol’ is delivered to participants reporting at-risk alcohol use. It contains (1) behavioural feedback on the participant’s alcohol use in relation to guidelines<sup>41 46</sup> and others, and (2) motivation-enhancing feedback on reducing alcohol use.
- ▶ Module ‘Smoking’ is delivered to participants reporting to be tobacco smokers currently. It contains (1) behavioural feedback and (2) motivation-enhancing feedback on quitting smoking.

Each module’s written feedback is supported by visualising elements. The profile module results in about an

½ A4 page; and the four HRB modules result in about 2–3 feedback pages each. To avoid overwhelming participants with multiple HRBs, a maximum of two HRB modules are selected per participant based on evidence-based decisions and participant’s preference ([figure 3](#)). In detail, participants with more than 2 HRBs receive at least one of the two modules for which efficacy has been established, that is, ‘alcohol’ or ‘smoking’, depending on the following decision rules: (1) If either at-risk alcohol use or tobacco smoking is present, the according module is selected by the system. The second module is determined by asking participants ‘What part of your lifestyle would you have to change to achieve the largest impact on your quality of life?’ with two response options (physical activity; diet). (2) If both at-risk alcohol use and tobacco smoking are present, participants are first asked to choose between alcohol use and tobacco smoking by using the above question, and are asked again to choose between the remaining two or three options. (3) There is one exception to both rules: In case of AUDIT-C scores  $\geq 8$ , the system does not preselect the module ‘alcohol’ (rule 1) or tobacco smoking is preselected (rule 2) as the efficacy of the module ‘alcohol’ has not been established for at-risk users with AUDIT-scores  $\geq 8$ .<sup>47</sup>

Intervention development study PAL-Survey: The preceding developmental process included the conduction of a survey on HRBs and TTM measures among 256 general hospital patients (PAL-Survey): (1) to test the questionnaires and/ or German translations concerning the assessment of HRBs and TTM-based measures for the new modules ‘inactivity’ and ‘diet’; (2) to obtain normative data for the TTM-measures required for normative feedback as part of the modules ‘inactivity’ and ‘diet’; and (3) to obtain information on the participants preferences concerning feedback in case multiple HRBs occur.<sup>48</sup>

## Intervention delivery

After baseline, participants receive the first part of the computer-generated feedback. One and 3 months later, participants are contacted by email to fill in intervention questionnaires. If contact attempts by email fail or if participants prefer to be phoned, they are contacted for CATIs by a research assistant to facilitate intervention retention. The 1-month and 3-month feedback letters are sent out accordingly, either online or by ordinary mail. Intervention delivery is discontinued when participants do not wish to participate any longer.

## Follow-ups

Follow-ups are conducted 6 months after initial contact by self-administered online questionnaires or CATIs. Follow-up participation is enhanced by sending out prepaid incentives (ie, previously self-selected 10 Euro-vouchers) along with postal reminders. Paying monetary incentives is an evidence-based strategy to increase study participation, to reduce selectivity and thereby to increase the informative value of the study. Delivering monetary

Table 2 Content of PAL intervention modules

Modules	Target	For whom	Behavioural feedback			Motivational feedback			
			Recommendations	Behaviour	Normative	Ipsative	TTM constructs	Normative	Ipsative
Profile HRBs	Provide information on overall lifestyle	All	Listed below	Overview over individual HRBs	-	Month 1 Month 3	-	-	-
Physical inactivity	Increase physical activity	Participants with insufficient physical activity	≥150 or ≥75 min of moderate or vigorous activity per week or an according combination of both <sup>38</sup>	No of minutes per week	Baseline	Month 1 Month 3	Stage of change Processes Decisional balance Self-efficacy Plan to change	Baseline	Month 1 Month 3
Unbalanced diet	Increase vegetable/ fruit intake	Participants with low vegetable and fruit intake	5 servings/day <sup>39 40</sup>	Servings of vegetable and fruit per day	-	Month 1 Month 3	Stage of change Processes Decisional balance Self-efficacy Plan to change	Baseline	Month 1 Month 3
	Increase fibre, decrease fat, salt, sugar intake*	Participants with none of the 4 HRBs	Fat <30% of total energy intake Fibre ≥30g/ day Salt <5g/ day Sugar <50g/ day <sup>39,40 43-45</sup>	Fibre intake, Salt intake, Fat intake, Sugar intake	-	Month 1 Month 3	-	-	-
At-risk alcohol use	Decrease alcohol use	Participants drinking alcohol at-risk	≤7/14 drinks per week and <4/5 drinks per drinking occasion for women/men <sup>41 46</sup>	Drinks per drinking day; Heavy drinking occasions; Risk of own drinking	Baseline Month 1 Month 3	Month 1 Month 3	Stage of change Processes Decisional balance Self-efficacy Plan to change	Baseline Month 1 Month 3	Month 1 Month 3
Tobacco smoking	Quit smoking	Participants currently smoking	Non-smoking	No of cigarettes	Baseline	Month 1 Month 3	Stage of change Processes Decisional balance Self-efficacy	Baseline	Month 1 Month 3

\*The behavioural feedback on the intake of fibre, fat, salt and sugar is not only delivered to participants with insufficient vegetable and fruit intake but also to participants with none of the four HRBs (alcohol, smoking, insufficient vegetable and fruit intake, physical inactivity) in addition to the behavioural feedback provided by the module 'Profile'. HRBs, health risk behaviours; PAL, proactive automatised lifestyle intervention; TTM, transtheoretical model of intentional behaviour change.

Health Risk Behaviors (HRBs)							Intervention Modules
physical inactivity, low vegetable and fruit intake, at-risk alcohol use, tobacco smoking							Month 0, 1, 3
None							P *
							P
							P
							P
							P
							P
							P
							P
							P
							P
							P
							P
							P

- Module selected by system due to <3 HRBs
- Module selected by system due to 3 HRBs with no and AUDIT-C<8
- Module selected by system due to ≥3 HRBs with no or AUDIT-C≥8
- Module selected by participant
- No circle: HRB is neither selected by system nor by participant for intervention
- P Module „Profile“ contains integrative behavioral feedback on all 4 HRBs

**Figure 3** Composition of PAL feedback modules based on co-occurrence of health risk behaviours and selection by system and participant preference. \*Month 0 only. AUDIT-C, Alcohol Use Disorder Identification Test-consumption; PAL, proactive automatised lifestyle intervention.

incentives before rather than after actual participation results in particularly high participation.<sup>49 50</sup>

### Measures

Computer-assisted assessments described in more detail in table 3 are based on self-report. To increase the reliability of self-report, standardised and validated psychometrical measures are used if available. At baseline, assessments are self-administered. Patients are introduced into the handling of the questionnaire using tablet computers and if required, they may receive support by research assistants. Intervention assessments at months 1 and 3 may either be self-administered online or through CATIs. They primarily include assessments required for individualised feedback. Follow-ups after 6 months are conducted through CATIs if possible or self-administered online. It includes most of the baseline assessment plus assessments on satisfaction with the intervention. All research assistants involved in recruitment and data collection are trained and supervised on a weekly basis.

### Primary outcomes

Primary outcomes are intervention reach and retention. Reach is measured using observed numbers and proportions of participants reached among all eligible patients at baseline. Retention is measured using observed numbers and proportions of participants who continued participation at months 1 and 3. These indicators for intervention reach and retention are analysed for the total sample and subgroups of particular interests, such as participants with low school education.

### Secondary outcomes

Secondary outcomes are based on self-report and include satisfaction with the intervention after 6 months, and changes in HRBs, health and motivation (table 1).

Satisfaction with intervention is assessed at month 6, using a 29-item measure based on.<sup>51 52</sup> The modified and adapted measure, assesses satisfaction with intervention process (ie, intervention characteristic, dose and format, usage, overall) and intervention outcome (ie, discomfort, attribution of outcomes to treatment).

Physical activity is assessed using the European Health Interview Survey-Physical Activity Questionnaire<sup>53 54</sup> plus three self-created items on physical effort. The questionnaire includes eight items on sitting, muscle strengthening activities and frequency and quantity of walking and cycling for transportation purpose and of sports activity in leisure time. As it does not differentiate between moderate and vigorous activity and this differentiation is required for feedback according to WHO recommendations (as reported above), three items with three response categories separately assess the effort used for walking, cycling and sports activity. To weigh minutes reported for walking and cycling, the item asks ‘When doing so, do you breathe or sweat more than normal or does your heart beat faster?’. The response category ‘No, usually not’ indicates that the minutes reported may not be counted as moderate physical activity according to WHO recommendations, and are excluded from the total minutes of physical activity. ‘Yes, frequently’ indicates that the number of minutes reported may in part be considered as

**Table 3** PAL self-report measures for each measurement time point

Measure	Reference; modifications	No of items	Target group at month			
			0	1	3	6
Health risk behaviours						
Physical inactivity (I)						
European Health Interview Survey-Physical Activity Questionnaire	Item seven modified: active day instead of week <sup>53</sup>	8	All	All	All	All
Physical effort	Own construction	3	All	All	All	All
Unbalanced diet						
Vegetable, fruit (V)	Own construction, similar to, assesses servings of food containing fat, fibre, salt and/ or sugar per day/week; complemented by descriptive examples <sup>55</sup>	2	All	All	All	All
Fat, fibre, salt, sugar		14	All	All	All	All
At-risk alcohol use (A)						
Alcohol Use Disorder Identification Test- Consumption	Item three gender-specific: ≥4 women, ≥5 men <sup>56 57</sup>	3	All	All	All	All
Time-Line-Follow-back past month	Based on <sup>60</sup>	3	A	A	A	A
Exploration abstinence	Own construction	2	Abstainers	–	–	–
Tobacco smoking (S)						
Smoking status	<sup>53 61</sup>	1	All	All	All	All
Cigarettes per day	<sup>53 61</sup>	2	S	S	S	S
Motivation modules (maximum of 2)						
Module Inactivity						
Staging algorithm	Adapted to physical activity from <sup>32</sup>	4	I	I	I	I
Processes of change	Own translation <sup>62</sup>	18	I*	I*	I*	I*
Decisional balance	Own translation <sup>62</sup>	9	I*	I*	I*	I*
Self-efficacy	Own translation <sup>62</sup>	6	I*	I*	I*	I*
Module diet (vegetable and fruit intake)						
Staging algorithm	Own translation; modification based on <sup>63 64</sup>	1	V	V	V	V
Processes of change	Own translation <sup>63</sup>	14	V*	V*	V*	V*
Decisional balance	Own translation <sup>63</sup>	8	V*	V*	V*	V*
Self-efficacy	Own translation <sup>63</sup>	6	V*	V*	V*	V*
Module alcohol						
Staging algorithm	Described in; developed according to refs <sup>32 64 65</sup>	4	A	A	A	A
Processes of change	<sup>66 67</sup>	16	A*	A*	A*	A*
Decisional balance	<sup>68 69</sup>	10	A*	A*	A*	A*
Self-efficacy	<sup>68 70</sup>	8	A*	A*	A*	A*
Module smoking						
Staging algorithm	Modification based on refs <sup>64 65 71</sup>	2	S	S	S	S
Processes of change	<sup>71 72</sup>	19/24	S*	S*	S*	S*
Decisional balance	<sup>71</sup>	8	S*	S*	S*	S*
Self-efficacy	<sup>71</sup>	9	S*	S*	S*	S*
Intervention aspects						
Module selection						
Expected impact of change on life	Own construction	2	≥3 HRBs	–	–	–
Acceptance and satisfaction	Based on refs <sup>51 52 73</sup>	29	–	–	–	All
Health						
Body weight and height		2	All	–	–	All
General health	<sup>74</sup>	1	All	–	–	All

Continued



Table 3 Continued

Measure	Reference; modifications	No of items	Target group at month			
			0	1	3	6
Sick days past 6 months	Described in <sup>28</sup>	1	All	–	–	All
Non-communicable diseases	Own construction, examples from <sup>53</sup>	4	All	–	–	All
Mental health inventory	<sup>75 76</sup>	5	All	–	–	All
Utilisation medical care	Modified time frame: 6 instead of 12 months <sup>53</sup>	6	All	–	–	All
Sociodemographics						
Sex, age		2	All	All	All	All
Family status, children		3	All	–	–	–
School education, employment	<sup>77</sup>	4	All	–	–	–
Migrant background		1	All	–	–	–

\*When health risk behaviour present and selected for intervention.  
 A, at risk alcohol use present; I, physical inactivity present; PAL, proactive automatised lifestyle intervention; S, tobacco smoking present; V, insufficient vegetable and fruit intake present.

moderate activity, and reported minutes are multiplied by 0.5. ‘Yes, almost always’ indicates that minutes reported may be considered as moderate activity, and minutes are calculated as reported. To weigh minutes reported for sports, the item asks ‘When doing so, how much stronger than normal do you breathe, sweat or does your heart beat?’. The response category ‘A little stronger’ indicates moderate activity, and minutes are calculated as reported. ‘Much stronger’ indicates vigorous activity and minutes reported are multiplied by 2.0. ‘Sometimes so and sometimes so’ indicates a combination of moderate and vigorous activity, and minutes are multiplied by 1.5. When summing up all three products, the total number of minutes of moderate activity per week is obtained.

Diet is assessed using a diet screener, a measure developed similar to the Mediterranean Diet screener.<sup>55</sup> This 16-item diet screener was needed to provide a brief measure assessing the intake of fat, fibre, salt and sugar. Participants are required to report the number of servings of different foods per day or per week. Each item is supported by several examples of what one serving may include. The calculation of intake of fibre in gram is based on four items (vegetable, fruit, bread, other food rich in fibre), of fat in kilocalories on seven items (cheese, convenience food, salted snacks, eggs, fatty fish, red meat, processed meat, butter/ oil, milk), of salt in gram on six items (cheese, convenience food, salted snacks, red meat, processed meat, bread) and of sugar in gram on three items (sweets, added sugar, sweetened drinks). Vegetable and fruit intake of less than five servings a day is used as indicator of HRB.

Alcohol use is assessed using the Alcohol Use Disorder Identification Test-Consumption.<sup>56</sup> Women with sum scores of 4 and higher and men with values of 5 and higher are considered HRB, that is, to drink alcohol at-risk.<sup>57</sup>

Tobacco smoking is assessed by smoking status and the number of cigarettes per day. Any occasional or daily smoking is considered HRB.

An overall HRB index, that is, the sum of the current HRBs is created. Insufficient physical inactivity, insufficient With each HRB counted as 1, the index ranges between 0 and 4.<sup>58</sup> Test characteristics of this particular index are investigated as part of the project. Similar measures have been found to predict individuals’ risks of various cancer diseases in women and men for example.<sup>59</sup>

Measures on health include body weight and height to calculate the body-mass-index, general health, mental health, number of sick days in previous 6 months, non-communicable diseases, utilisation of healthcare. These are assessed at baseline and at month 6.

Measures on motivation include packages of four TTM measures assessing motivational stage of behaviour change, decisional balance, processes of change and self-efficacy for each HRB (table 3). The assessment is required to generate motivation-enhancing feedback as part of the intervention. While stage of change is assessed among all participants reporting the according HRB, decisional balance, processes of change and self-efficacy are assessed among those participants assigned to the according intervention module. The TTM measures for the modules ‘alcohol’ and ‘smoking’ have been used previously<sup>30 31</sup>; those for the modules ‘inactivity’ and ‘diet’ were translated from English into German, tested and modified as part of the intervention development study PAL-Survey.

### Data management, monitoring and safety

Assessment data are entered electronically, that is, either through tablet computers, online or CATIs. To enable the determination of the proportion of patients reached versus not reached for the intervention, a temporary contact list is used. When data collection is finished, the doctoral students will conduct data cleansing, including data plausibility checks, labelling of variables and values. A codebook is provided.

To ensure that all staff involved with collection, entry and management of data adhere to the protocol and to



discuss upcoming issues, weekly meetings are conducted. Given little risks from behavioural interventions, a data monitoring committee is not needed, the study is not expected to be stopped prematurely, and no ancillary or post-trial care is planned.

The study procedures concerning usage, storage and delivery of data have been approved by the local data security appointee. Confidentiality before, during and after the trial is ensured through, for example, pseudonymisation, storage of informed consent forms with linking participant identifying information and participant ID in a steel locker with access limited to an independent trustee, separate storage of participant identifying information and research data, anonymised evaluation of data, non-release of participant identifying data outside the study, security of all databases by password-protected access systems.

The principal investigator will have full access to the complete final dataset and oversee the intrastudy data sharing process, with input from the data management team. Full access to participant identifying information is limited to an independent trustee. To ensure confidentiality, data dispersed to project team members are blinded of any identifying information.

### Statistical analyses

Intervention reach and retention are determined by descriptive statistics, namely (1) the proportion of participants among eligible patients and (2) the proportion of participants who continue participation after hospitalisation among all initial trial participants. Equity in reach and retention are measured with regard to school education and other sociodemographics using multivariate regressions. Satisfaction with the intervention is determined by descriptive statistics. To analyse change in motivational measures, HRBs and health measures over four time points in 6 months, latent growth modelling is applied, allowing the inclusion of all initial participants regardless of missingness using maximum likelihood estimation.

### Sample size determination

The longitudinal sample to be recruited is 175 participants irrespective of HRB profile and reason of hospital admission. The sample is expected to be large enough to investigate the acceptance of the PAL intervention in terms of reach, retention and satisfaction, to provide a sufficient number of cases for latent growth modelling, and to have sufficient power (80%,  $\alpha=0.05$ , two tailed) to detect small-sized to medium-sized effects (Cohen's  $d=0.38$ ) in mean differences between two independent groups, for example, participants versus non-participants. Expecting 90% of the eligible patients participating in the survey, and 80% of these to participate in the intervention study as achieved in own previous studies,<sup>32</sup> we expect to approach about 243 patients over 2 months.

### ETHICS AND DISSEMINATION

Intervention participants provide written informed consent. The ethical commission of the University Medicine Greifswald and data safety appointee approved the study procedures described above (BB 024/17; BB 024/17a).

Results will be disseminated via publication in international scientific journals and presentations on scientific conferences. Substantive contributions to the design, conduct, interpretation and reporting of the trial are recognised through the granting of authorship on the final trial report. In terms of reproducible research, anonymised data and supporting information including the codebook and analytical code may be made available on reasonable request.

**Acknowledgements** We very much appreciate our student assistants Sarah Habicht and Greta Otto who provided support in designing pictograms for the intervention.

**Contributors** JF-A and UJ designed the study and acquired funding. JF-A, FK and AT initiate the study design, and KS and MS help with implementation. JF-A, FK, AT, KS, MS and KK integrated and designed new intervention modules for the purpose of this study. CG programmed the electronic assessment and intervention. JF-A wrote the first draft of the study protocol. All authors contributed to refinement of the study protocol and approved the final manuscript.

**Funding** JF-A and UJ receive funding from the German Cancer Aid (grant no. 70113382, 70114206) to develop and test the PAL intervention among general hospital patients. We acknowledge support for the Article Processing Charge by the German Research Foundation and the Open Access Publication Fund of the University of Greifswald (grant no. N/A).

**Disclaimer** The funders have no role in study design; collection, analysis and interpretation of data; writing the report; and the decision to submit the report for publication.

**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication** Not applicable.

**Provenance and peer review** Not commissioned; peer reviewed for ethical and funding approval prior to submission.

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