Clinical Study Protocol

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A Mobile Intervention for Patients with Peripheral Artery Disease (I-PAD): a Prospective Randomized Open Blinded End-point (PROBE) study

I. BACKGROUND AND SIGNIFICANCE

Peripheral artery disease (PAD) is a highly prevalent atherosclerotic syndrome with an estimated global population burden of ~200 million people (1). Patients with PAD are at heightened risk for adverse cardiovascular and limb events and impaired quality of life (2). Cigarette smoking is the most important modifiable risk factor for PAD. Patients with PAD who smoke have higher disease progression rates, greater risk of complications, poor post-procedural outcomes, compromised functional status, and increased hospitalizations, accounting for a higher patient and societal burden (3).

A significant goal of PAD treatment includes risk factor modification and prevention of cardiovascular events. Guideline directed therapy includes cardioprotective pharmacotherapies (i.e., antiplatelet therapy; statins; and blood pressure control, preferably with angiotensin-converting enzyme inhibitors (ACE-I) or angiotensin receptor blockers (ARBs)), and lifestyle modification (i.e., changes in diet, physical activity, and smoking cessation) (2). Nevertheless, adherence to pharmacologic and lifestyle recommendations in PAD is uncertain (4). Effective non-pharmacologic therapies for PAD also exist, including smoking cessation, exercise support, and diet counseling (5). However, limited data is available on mobile applications offering digitally delivered lifestyle change support, including a structured exercise program and smoking cessation support (6). This study aims to digitally provide lifestyle change support, including a structured and PAD-focused lifestyle program and smoking cessation support via a mobile platform (Sidekick Health) with the primary aim to increase patients' walking ability and secondary aims to reduce smoking and improve medication adherence.

II. SPECIFIC AIM

The specific aim is to determine whether a 12-week digitally delivered behavior change intervention for patients with peripheral artery disease increases walking ability, reduces smoking, improves quality of life and improves medication adherence. A follow-up visit after 12 months will be planned, to assess longer term effect on outcomes and healthcare cost.

Hypotheses

a) At the end of the 12 weeks, the interventional arm will reach a clinically meaningful change in walking ability, as compared to controls, measured by a change in the 6-MWT at twelve-week, and 12 months; the minimal clinically important difference (MCID) is defined as +12m (7).

b) At the end of the 12 weeks, ≥15% interventional treatment arm participants will give up smoking or have significantly reduced their daily smoking compared to less than ≤10% in the control arm.

c) At the end of the 12 weeks, ≥50% of interventional treatment arm participants will improve their medication adherence from pre- until post-intervention as compared to <30% in the control arm.

d) Healthcare cost will be reduced at 12 month follow-up in the intervention arm.

III. METHODOLOGY

We will implement a randomized controlled study of a 12-week lifestyle intervention for patients with peripheral arterial disease, delivered via the digital platform Sidekick Health. Participants will be recruited and randomized in a 1:1 manner to the digitally delivered intervention + standard of care or standard of care only. The standard of care group will receive an information leaflet on important lifestyle factors for PAD and smoking cessation and medical adherence will be encouraged by the health care provider. The interventional arm will receive a digital program delivered to their mobile phone alongside standard of care. Replicating a real-life scenario a personalized approach will be applied in the interventional arm, especially regarding smokers. Therefore, two pathways are possible in the interventional arm in this trial, one for smokers who want assistance in smoking cessation (PAD-SC) and another for non-smokers or those who smoke and do not desire to quit (PAD-Reg). Patients will be followed up at 12 weeks. We aim to do a separate follow-up at twelve months. The primary outcome will be a change in pain-free and maximal walking ability, measured by the 6-minute walking test. Secondary outcomes will include smoking status change (in PAD-SC group as compared to the control arm), medication adherence and lifestyle changes (increased physical activity, changes in self-assessed stress/energy/sleep quality levels), health-related quality of life, and a reduced need for hospitalization or revascularization due to PAD at 12 months of follow up.

Subject selection

Individuals willing to participate and who provide written informed consent to the study will be further assessed and screened based on the inclusion and exclusion criteria presented in Table 1.

Table 1. Participant Criteria

Inclusion	Exclusion
Adults with confirmed PAD referred to a vascular surgery unit for evaluation and treatment, currently on best medical treatment and own/have access to a mobile smartphone	Critical limb ischemia, prior amputation, or other diseases/ impairment that limit the walking ability and the 6-minute walk test's proper conduct
Stable PAD disease and limb symptoms during the last 3 months.	Cognitive impairment
PAD is the activity-limiting disease	Prior revascularization less than one year ago
Abnormal resting ankle-brachial index (≤0.90), falsely elevated above 1.3 or a 30% post-exercise ABI reduction.	A planned revascularization procedure during the upcoming 12 months (known at baseline)

Subject enrollment

Patients will be recruited by a clinic nurse or a medical doctor at participating centers (via telephone or during a scheduled in-person visit). Once agreed to participate and after signing informed consent, then the inclusion and exclusion criteria will be explored. Patients failing the screening process (do not meet the inclusion/exclusion criteria) may not participate in this study. Reasons for screen failure will be documented, but no other data will be collected. Participants who meet the criteria will be randomized to intervention or usual care in a 1:1 manner.

Based on a G*power analysis, the total number of patients in the two groups (intervention and control) will be 134, 67 in the intervention group and 67 in the control group, with an anticipated effect size of f = 0.15, alpha = 0.05, power = 0.80 and correlations between time points (baseline and final timepoint) estimated at r=0.25. Foreseeing an attrition rate of 15%, we aim to recruit 155 patients to the trial.

Study procedures

All participants:

After recruitment, measurements and data collections will occur at each clinic by a experienced clinic or research nurse, as shown in table 2 and further detailed under section VIII. Furthermore, a 6-minute walking test will be administered by a trained clinic nurse at baseline, after 12 weeks and for a separate follow-up at 12 months. The American Thoracic Society protocol for the 6-minute walking test, modified for patients with intermittent claudication (IC), will be used. The 6MWT has excellent test-retest reliability for patients with IC. (8, 9). A central computerized procedure will randomly assign participants to treatment arms, stratified for study site and smoking status.

Intervention:

Participants will be instructed to download the SKH mobile app, and they will receive an access code to activate the PAD lifestyle change program. After the first week of the program, participants who smoke will be offered to incorporate smoking cessation support into their PAD program. These changes are minor and not intended to divide the intervention group in two but instead personalize the experience. Personalization of the program is essential for engagement and to deliver the most meaningful impact on clinical outcomes. The program aims to empower positive lifestyle change by gamification, altruistic rewards, and engaging content with relevant tasks or missions to be completed. Beyond this, all patients in the interventional arm will also receive standard of care as defined below for the control arm.

Participants in the intervention group will also be asked to do a separate and virtually delivered 6-minute walking test to validate the digital in-app 6MWT.

Control:

All patients in the control arm will receive best medical treatment including start or optimization of secondary preventive pharmacotherapy, smoking cessation advise and advise on modifiable risk factors. The control arm will also receive an information leaflet about relevant lifestyle modifications for PAD. After baseline measurements and data collection, there will be no scheduled visits by a health care provider until week 12.

Table 2. Timing of Proposed Data Collection and Instruments Used

Data collection/Instruments	Baseline	Post-Intervention (after week 12)	12-month follow-up
All participants (intervention and control)			
Demographic and Clinical/Medical Baseline Information (e.g., tobacco use, other risk factors, and comorbidities)	Yes	Yes	Yes
6-Minute Walking Test	Yes	Yes	Yes
Vascular Quality of Life Questionnaire (VascuQoL-6)	Yes	Yes	Yes
Morisky Medication Adherence Scale (MMAS-8)	Yes	Yes	Yes
Quality of life questionnaire – assessed by EQ5D5L	Yes	Yes	Yes
Assessment of health literacy (HLS-EU-Q16 Swedish version)	Yes	-	-
Carbon Monoxide breath monitor (smokers only)	Yes	Yes	Yes
Smoking Readiness to Quit Ladder (smokers only)	Yes	Yes	Yes
Daily frequency of cigarettes smoked (smokers only)	Yes	Yes	Yes
Intervention arm only			
In-app 6-minute walking test	Yes	Yes	Yes
Free-living physical activity (measured as total step count per day)	Yes (week 1)	Yes	-
In-app metrics (e.g. stress/sleep/energy level self-assessment)	Yes (week 1)	Yes	-

Measures – copies of questionnaires will be included in this protocol when finalized in section VIII below (Study Questionnaires)

IV. BIOSTATISTICAL ANALYSIS

Variables to be collected

Participants' demographic and background information, including age, gender, height, weight (and BMI), tobacco use, co-morbid medical or psychiatric conditions, and information on any current medical therapy they may or may not be receiving will be collected. All participants should be on the best medical PAD treatment available for them, and the control arm will receive an information leaflet about relevant lifestyle modifications for PAD. A 6MWT, questionnaires, and validated survey instruments (10) will be administered both pre-and post-intervention and 12 months from the start of the intervention.

Primary Outcomes (Intervention KPIs)

As far as possible, evaluation of endpoints will be done by evaluators blinded to the treatment assignment (PROBE design).

- Walking Ability: Change in patients objectively measured walking ability (measured by the 6-Minute Walk Distance Test) from pre- to post-intervention and 12 months.

Secondary Outcomes

- Smoking status: Change in patients' daily smoking patterns from pre to post-intervention and at twelve months. This will be based on information from the patient, supported by read-outs from the carbon monoxide breath monitor at baseline, 12 weeks and one year.
- Medication adherence improvement.
- Lifestyle behavioral changes (measured in-app):
    - Changes in free living physical activity, measured as total step count per day (from baseline to week 12)
    - Changes in self assessed stress levels, measured on an ordinal scale from 0-10 (from baseline to week 12)
    - Changes in self assessed energy levels, measured on an ordinal scale from 0-10 (from baseline to week 12)
    - Changes in self assessed sleep quality, measured on an ordinal scale from 0-10 (from baseline to week 12)

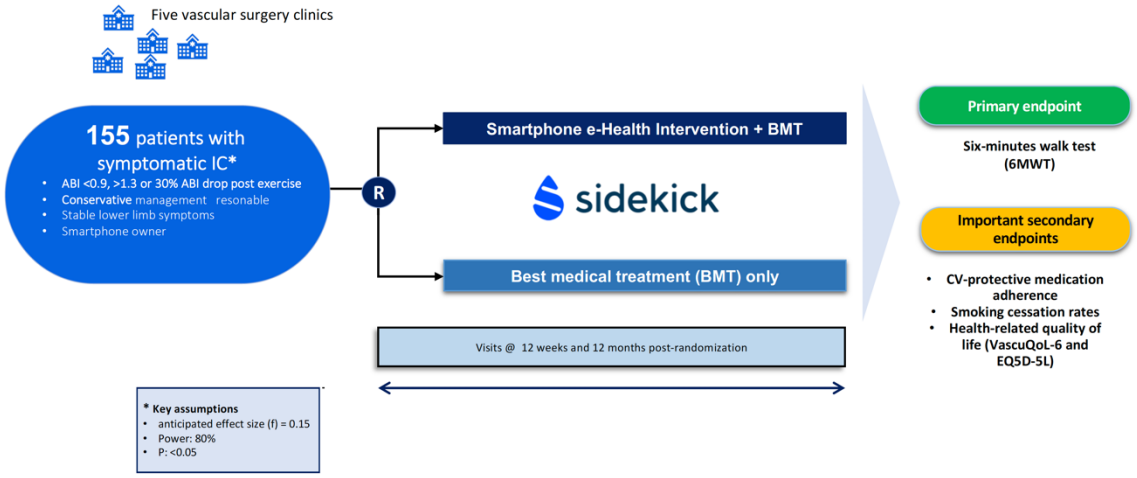
- Disease-specific health-related quality of life.
- Increased readiness to quit smoking.
- Comparing outcomes to health literacy.
- Comparing healthcare costs between groups. Following completion of the long-term follow-up at 12 months for all patients, a separate cost-effectiveness analysis will be undertaken, based on the prospectively collected EQ5D-5L data and accumulated costs per patient as registered in the participating hospital's cost-per-patient databases. Quality Adjusted Life Years (QALYs) and Incremental Cost-Effectiveness Ratio (ICER) will be the main analyzed endpoints.

Retention and Engagement

- Program uptake (number of app downloads, how many participants/potential quitters registered (including gender and age)
- Length of program participation
- Program usage patterns (how often do people visit, how many tasks are performed, which tasks (videos, daily tasks, other) are used/accessed, etc.)
- Pre/post assessment of medication therapy (as registered medication taken)

End of study

The formal trial completion is when the recruited patients have completed the 12-week intervention, but an extended follow-up at twelve months from study start will also be arranged.



Statistical Methods

Analyses will be performed according to the intention-to-treat principle and per-protocol analyses. Baseline characteristics and raw score questionnaire outcomes will be summarized as mean and SD for continuous measures and absolute numbers and percentages in each group. Changes in each outcome between baseline, post-intervention, and later a 12-month follow-up will be compared between and within the groups using t-tests or non-parametric statistical tests as appropriate. For the between-group differences, 95% Confidence Intervals will be reported. Correlations will be run to explore relationships between variables. For the primary outcome analyses, Ancovas or Mixed Anovas (repeated measures anovas) will be used, correcting for covariates that are significantly different between groups. The size of the change in HRQoL will be related to minimal important change values for the VascuQoL-6. It will be further assessed through effect size calculations (effect size=the difference in mean values between baseline and follow-up, divided by the SD at baseline). Cohen's criteria for interpreting effect sizes will be applied (small, 0.2–0.5; moderate, 0.5–0.8 and large, over 0.8). The a priori level for statistical significance will be set at a 2-sided P<.05.

V. RISKS AND DISCOMFORTS

We expect minimal to no risks and discomforts to be associated with this study. The lifestyle/behavioral change program is guideline-compliant for PAD patients and has

been reviewed by several medical doctors, behavioral scientists, and specialists in vascular surgery. Psychosocial risks will be minimal as well.

VI. POTENTIAL BENEFITS

Potential Benefits to Participating Individuals

The hope is that the intervention will increase participants' walking ability, reducing IC symptoms and prevent revascularization, empower participants to change their lifestyle and smoking patterns for the better, or that they will quit smoking altogether. Further, this intervention may also improve other patient-reported outcomes (e.g., reduce stress, improve sleep) without causing significant harm. Although the expected benefits are limited for patients that are allocated to usual care in the study, the enhanced follow-up at 12 weeks and 12 months may allow for a more careful evaluation and subsequent treatment of their condition following the end of study.

Potential Benefits to Society

The hope is that this program will contribute to a healthier population. If the Sidekick PAD program proves efficient because it is highly scalable, it may alter the disease progression and improve millions' lives. The program may also positively impact the environment if participants quit smoking as cigarettes are a considerable environmental pollutant.

VII. MONITORING AND QUALITY ASSURANCE

SKH will regularly monitor study data accuracy and will guarantee safe study data storage. Furthermore, SKH will monitor and amend potential technical issues that hinder participants' accurate access to and using the smartphone application and its full functionality. As soon as the opportunity arises, the obtained data will be anonymized and removed from personal health information. All participants will be de-identified and assigned research subject IDs (e.g., participant 1). Only the study staff will have access to information that can link the subject IDs with the personal health information, saved on a secure, shared drive. Further, clinic staff/providers will report any adverse events using standard procedures.

VIII. VARIABLES TO BE COLLECTED

Demographic/clinical/anthropometric variables:

1. Age
2. Gender
3. Smoking status
4. Height
5. Weight
6. BMI
7. Waist circumference
8. Ankle-brachial index (ABI)
9. Comorbidities (obesity, diabetes type 1 or 2, other CVD)
10. Relevant medications. Information on medical therapies will focus on medicines important for secondary prevention of PAD, will not collect specific dosing, and will be dichotomously (yes/no) categorized as follows:
    a. Antihypertensive agent(s)
    b. Antidiabetic agents (both peroral and injectables will be categorized into one single category)
    c. Lipid lowering therapy (statins, ezetimibe and PCSK-9 inhibitors will be categorized into one single category)
    d. Antiplatelet therapy
        i. Single antiplatelet therapy
        ii. Dual antiplatelet therapy
    e. Anticoagulation therapy
        i. Low dose rivaroxaban
        ii. Therapeutic anticoagulation
11. Health literacy status
12. Educational level (primary school, high school, higher education)
13. Work status (working, unemployed, retired)

In-app activity collected:

Self-reported measurements	Age, gender, height, weight, sleep quality, stress level, energy level.
Logged items	Fruits, vegetables, nuts, and seeds consumed. Physical activity tasks. Stress reduction tasks. Food photos, diet improvement tasks.

Missions/tasks	Some involve in-app logging (see above), others not logged.
6 MWT in-app	A 6-minute walking test feature available in the SK app uses GPS outdoors, roughly assessing cardiorespiratory fitness.

Measurements and Questionnaires:

1. Protocol for a 6-minute walking test (see appendix A)
2. Vascular Quality of Life Questionnaire (VascuQoL-6)
3. A standard measurement of health status (EQ-5D-5L)
4. The European health literacy survey (HLS-EU-Q16 Swedish version)
5. Morisky Medication Adherence Scale (MMAS-8)
6. Readiness to quit smoking (The Contemplation Ladder)

IX. REFERENCES:

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QUESTIONNAIRES:

VASCUQOL-6

1 *Because of the poor circulation in my legs, the range of activities that I would have liked to do in the past two weeks has been....*

1 ☐ Severely limited – most activities not done
2 ☐ Moderately limited – several activities not done
3 ☐ Very slightly limited – very few activities not done
4 ☐ Not limited at all – have done all the activities that I wanted to

2 *During the past two weeks, my legs felt tired or weak....*

1 ☐ All of the time
2 ☐ Some of the time
3 ☐ A little of the time
4 ☐ None of the time

3 *During the past two weeks, because of the poor circulation in my legs, my ability to walk has been....*

1 ☐ Totally limited, couldn't walk at all
2 ☐ Very limited
3 ☐ A little limited
4 ☐ Not at all limited

4 *During the past two weeks, I have been concerned about having poor circulation in my legs....*

1 ☐ All of the time
2 ☐ Some of the time
3 ☐ A little of the time
4 ☐ None of the time

5 *During the past two weeks, because of the poor circulation in my legs, my ability to participate in social activities has been....*

1 ☐ Totally limited, couldn't socialize at all
2 ☐ Very limited
3 ☐ A little limited
4 ☐ Not at all limited

6 *During the past two weeks, when I have had pain in the leg (or foot) it has given me...*

1 ☐ A great deal of discomfort or distress
2 ☐ A moderate amount of discomfort or distress
3 ☐ Very little discomfort or distress
4 ☐ No discomfort or distress

Each question is scored 1-4. When using the VQ6, the sum of each individual question score is used to generate a 'Total' Quality of Life Score. A higher value indicates better health status.

EQ-5D-5L

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

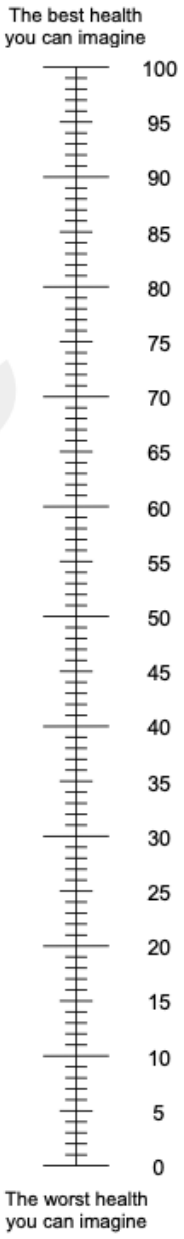
I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Please mark an X on the scale to indicate how your health is TODAY.
- Now, write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



EUHL16

On a scale from very easy to very difficult, how easy would you say it is to: …

1. Very difficult 2.Difficult 3.Easy 4 .very easy 5.don't know

a. find information on treatments of illnesses that concern you?

b. find out where to get professional help (such as doctor, pharmacist or psychologist) when you are ill?

c. understand what your doctor says to you?

d. understand your doctor's or pharmacist's instruction on how to take a prescribed medicine?

e. judge when you may need to get a second opinion from another doctor?

f. use information the doctor gives you to make decisions about your illness?

g. follow instructions from your doctor or pharmacist?

h. find information on how to manage mental health problems like stress or depression?

i. understand health warnings about behavior (such as smoking, low physical activity and drinking too much)?

j. understand why you need health screenings (such as breast exam, blood sugar test or blood pressure)?

k. judge if the information on health risks in media (such as TV, internet or other media) is reliable?

l. decide how you can protect yourself from illness based on information in media (such as newspapers, leaflets, internet or other media)?

m. find out about activities (such as meditation, exercise, walking and pilates) that are good for your mental well-being?

n. understand advice on health from family members or friends?

o. understand information in the media (such as internet, newspapers and magazines) on how to get healthier?

p. judge which everyday behavior (such as drinking and eating habits, exercise etc.) is related to your health?

Morisky Medication Adherence Scale (MMAS-8)

You indicated that you are taking medication for your (identify health concern, such as "high blood pressure"). Individuals have identified several issues regarding their medication-taking behavior and we are interested in your experiences. There is no right or wrong answer. Please answer each question based on your personal experience with your [health concern] medication. Interviewers may self identify regarding difficulties they may experience concerning medication-taking behavior.

(Please circle the correct number)

	No=0	**Yes=1**
1. Do you sometimes forget to take your [health concern] pills?		
2. People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your [health concern] medicine?		
3. Have you ever cut back or stopped taking your medication without telling your doctor, because you felt worse when you took it?		
4. When you travel or leave home, do you sometimes forget to bring along your [health concern] medication?		
5. Did you take your [health concern] medicine yesterday?		
6. When you feel like your [health concern] is under control, do you sometimes stop taking your medicine?		
7. Taking medication everyday is a real inconvenience for some people. Do you ever feel hassled about sticking to your blood pressure treatment plan?		

8. How often do you have difficulty remembering to take all your medications? **(Please circle the correct number)**

Never/Rarely.....**0**

Once in a while.....**1**

Sometimes.....**2**

Usually.....**3**

All the time.....**4**

Source: Morisky DE, Ang A, Krousel-Wood M, Ward H. Predictive Validity of a Medication Adherence Measure for Hypertension Control. *Journal of Clinical Hypertension* 2008; 10(5):348-354.

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Fig. 1. MAQ (Medication Adherence Questionnaire)

Readiness to quit ladder (The contemplation ladder)

10	I have quit smoking.
9	I have quit smoking, but I still worry about slipping back, so I need to keep working on living smoke free.
8	I still smoke, but I have begun to change, like cutting back on the number of cigarettes I smoke. I am ready to set a quit date.
7	I definitely plan to quit smoking in the next 30 days.
6	I definitely plan to quit smoking in the next 6 months.
5	I often think about quitting smoking, but I have no plans to quit.
4	I sometimes think about quitting smoking, but I have no plans to quit.
3	I rarely think about quitting smoking, and I have no plans to quit.
2	I never think about quitting smoking, and I have no plans to quit.
1	I have decided not to quit smoking for my lifetime. I have no interest in quitting.