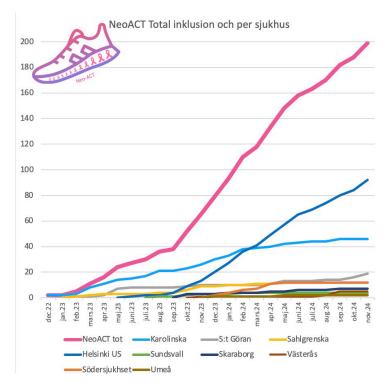


# Neo-ACT Newsletter December 2024



We have reached 206 randomised participants in the Neo-ACT trial. Thank you, Helsinki, for inclusion of the 200<sup>th</sup> participant!



We want to thank all participating sites for their contributions to the trial and wish everybody happy holidays!



#### **International expansion**

From January on, multiple sites will be opened in Germany, Australia and Scotland.

## Satisfaction questionnaire now in Dynareg

The Satisfaction questionnaire is now included in Dynareg, all patients will receive a question at the end of the questionnaires if they have been using the Vitala app, if they respond "Yes" the Satisfaction questionnaire will follow.

### **Updated exercise intervention**

In January 2025 we will launch a larger update of the Vitala mobile app including a distinct HIIT (high-intensity interval training) module. The new structure of the training sessions will be: 1) A warm-up including functional movements, 2) resistance training based on repetitions (not time), where participants will perform 2x12 repetitions for each exercise, 3) HIIT with bodyweight exercises that aim to increase the heart rate with 1-min intervals and 1-minute recovery in between, and 4) cool down/stretch. There will be different intensity levels for each HIIT exercise which allows the participants to increase or decrease the effort depending on how they feel at the time.

In addition to the app-based training in Vitala, voluntary online live and pre-recorded exercise sessions will be available for the participants starting in Jan 2025.

To further increase the intensity of the resistance exercises, participants receive two resistance bands each. These bands are provided to each site by Karolinska Institutet and sent by post. An e-mail with instructions for the resistance bands has been sent out to each site.

Participants assigned to the intervention group will be able to continue using Vitala for the entire enrolment period. Therefore, leave the participants' profile in the Vitala Care Portal unchanged once their intervention period is completed, and do not delete any participants from Care Portal. This is also important since the data must be available for further analysis. Please explain to participants that they need to renew their prescription themselves every 24 weeks by clicking "Renew" on the app's start page once the intervention has been completed. The app will automatically remind participants when it is time to renew the prescription.

#### **Updated Neo-ACT Study protocol**

An updated protocol (Version 1.5) has been submitted shortly to the Swedish Ethical Review Authority. In short, updates include:



- The recommended rest period between chemotherapy and exercise is shorted to 24 (instead of 48) hours. This is in line with (inter-)national guidelines as released by FYSS and ASCO.
- Addition of live and pre-recorded exercise sessions in the Vitala app (will be available from Jan 2025).
- Provision of Therabands to patients.
- Details of the updated exercise app structure

These modifications can be implemented now, since none of them are substantial changes that would require ethical approval before implementation.

When the new protocol has been approved by the respective ethical authorities, it will be distributed to the sites.

# **Updated ICF**

There will be a slight update of the ICF to clarify that participants need a <u>new</u> study-specific g-mail account, and that their digital approval (two-step authentication) may be required for the download of Fitbit data by the study team. It has also been added that voluntary on-line training sessions will be available, which follow the exact same structure as the app sessions. None of these updates/changes are substantial enough to require a renewed consent from already included participants.

When the new ICF has been approved by the respective ethical authorities they will be distributed to the sites.

## **Neo-ACT Homepage updated**

Please take a look at the updated Neo-ACT homepage! The documents under "Investigator Site File" have been updated including versions in different languages. These will be continuously updated when new versions become available.

The Neo-ACT homepage can be found here: Neo-ACT homepage





/Jana de Boniface, Renske Altena, Yvonne Wengström, Martina Rossland and Marie Westman