Very rapid inclusion in a clinical study with the help of eAuthentication (Bank-ID)

A study on 913 women with palpitations using new digital techniques.

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Conclusion

To speed up the inclusion rate, a fully web-based method including BankID for confirming identity was successfully used for the first time in a clinical study. Both the study participants and those running the study were very satisfied with the method.

Background

A new Swedish digital technique (Coala Heart Monitor) was used to explore if instant analysis and feedback of ECG analysis during palpitations can reduce symptoms and increase health related quality of life during a 2-month period.

The inclusion rate and implementation are very long for clinical or realworld studies. We wanted to test if a totally web-based method for inclusion and study implementation would be more efficient.

Method

With help of the NGO 1.6 million club during its yearly women's heart campaign and via press and social media, information of the study was spread nationally. We were offered via Karolinska Institutet to participate in the first study ever to use total eAuthen-

Aim

tication for study inclusion. Swedish personal BankID was used when confirming identity before signing informed consent via the patient information and completing webbased questionnaires. In Sweden, it is estimated that 80% of the adult population uses BankID

Results

- During the first weeks in May 2018, 2,387 women reported interest to participate
- 1,111 were included and study start was June 8 and study end November 30, 2018
- 913 women (age 21-88) completed the study during 2 months
- Reasons for drop-out were registered
- The ECG analyses were automatically performed via a well-validated algorithm with immediate feedback
- In total, 280,474 recordings (both chest and thumbs) were performed
- In general, participants had no problems with the digital approach in this fully web-based study and they were satisfied with the procedures.









