The Nausea Care App in patients receiving chemotherapy: A Randomized Controlled Trial

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43482

Source
ToetsingOnline

Brief title
Nausea Care App study

Condition

- Other condition

Synonym
Nausea, vomiting

Health condition

Patienten die chemotherapie krijgen voor mamma-, ovarium-, hodgkin-, non-hodgkin

Research involving
Human

Sponsors and support

Primary sponsor: Oncologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Chemotherapy, Nausea, NCA, Vomiting

Outcome measures

Primary outcome

The main study parameter include differences between NCAG and CG, regarding:

Chemotherapy induced nausea measured as a patient reported visual analoge scale

(VAS) and defined as a VAS equal or above 5 mm.

Secondary outcome

- Number of days including occurence of nausea.

- Number of days including occurrence of vomiting

- Number of days including usage of escape medication

- QoL-scores

Numbers and percentages of NCAG who:

- find the NCA easy to download

- find the instructions clearly described

- received information as requested

- find the NCA useful as a reminder for taking anti-emetics

- would recommend the NCA to other patients

Contacting the ward by NCAG and CG:

- number of days including extra visits

- number of days including extra phone calls

Study description

Background summary

Chemotherapy-induced nausea and vomiting (CINAV) have negative influence on Quality of Life (QoL). Despite counselling about anti-emetics, compliance is low. Patients forget or do not know when to take them. This suggests an alternative approach to this problem. In line with the growing influence of social media, an application for smartphones could be a useful method to inform and guide patients during their treatment. Therefore the Nausea Care App (NCA) is developed, to inform patients about anti-emetics and remind them to take them.

Study objective

Primary objective of this study is to determine whether there are differences in occurrence of nausea, vomiting, use of escape medication, and in quality of life between smartphone-owners who downloaded the App, and smartphone-owners who did not use the App.

Study design

Randomized Controlled Trial (RCT)

Intervention

The control group will receive standard verbal and written information about the anti-emetica schedule.

The intervention group will use the NCA an application, developed for smart-phone-using oncology patients who will be treated with nausea and vomiting inducing chemotherapy.
The NCA has several functions:
* Reminder to take anti-emetics
* Providing information about chemotherapy regimens and side-effects
* Providing information about the different types of anti-emetics and side-effects
* Confirming whether the patient has taken the prescribed anti-emetics
* Daily questioning whether the patient has vomited

* Daily questioning the level of nausea, using VAS-scores

Study burden and risks

Regarding the app as a guidance for patients, including information and reminders according to anti-emetics, it is considered to assist patients during their treatment. A risk might occur if the system contains errors, leading to false instructions. To eliminate this risk the app is tested thoroughly prior to conducting the RCT. Before the start of the study, the app was adjusted when necessary, which should reduce the risk to very low levels. Patients will be instructed, as usual, to contact the oncology department in case of ongoing nausea or other problems. The app will be designed explicitly for oncology patients receiving chemotherapy, therefore this study can not be conducted in healthy subjects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Adulta (18+)
- Diagnosed with oncologic disease
- Precription with AC, TAC, R-CHOP, ABVD, Taxol/Carboplatin
- Able to read and speake Dutch
- Own a smartphone (Iphone, Android)
- Capable to give written informed consent

Exclusion criteria

- Patient who received chemotherapy prior to study participation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	206
Type:	Anticipated

Medical products/devices used

Generic name:	Nausea Care App
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-03-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL55710.100.15