Testing a serious puzzle game for medication adherence in Rheumatoid Arthritis patients

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23326

Source
NTR

Brief title
GAMER study

Health condition

Rheumatoid Arthritis

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: AbbVie

Intervention

Outcome measures

Primary outcome

The primary outcome comprises the difference in proportion of non-adherent patients (less than 80% medication adherence) after three months in the intervention (serious game) group compared to usual care. Primarily, medication adherence will be measured using the

Compliance Questionnaire for Rheumatology (CQR). The CQR presented good validity when compared to an electronic medication monitoring device over a period of six months [22]. Currently, the CQR is regarded as a reliable instrument to assess self-reported adherence in RA.

Secondary outcome

Medication adherence (based on pill count) after three months:

Medication adherence is difficult to measure, since there is no commonly agreed standard for adherence assessment. The primary outcome on adherence is subjective and it is preferred to also assess adherence using an objective outcome. Therefore medication adherence will be assessed using the method of pill/injection counting for a single 'anchor' DMARD, in addition to the CQR questionnaire. Therefore patients will be supplied with a set and surplus amount of medication at the start of the anchor drug. They will be asked to commit to using this stock only during the study. At the end of the study patients will be asked to bring the remainder to the pharmacy and a count will be performed.

Medication adherence (based on CQR) at one month

As the intervention, playing 'Medi en Seintje' is voluntary the exact exposure to the intervention during the study period cannot be predicted. In order to better assess whether the intervention has an effect and because mobile games like 'Medi en Seintje' are subject to user engagement for retention of play, medication adherence is also assessed at one month using the CQR.

Beliefs about Medication Questionnaire (BMQ) at baseline, one and three months
The Beliefs about Medicine Questionnaire (BMQ) is also used. The BMQ assesses both beliefs about the necessity of medication and concerns about medication.

Patient reported outcome (based on RADAI questionnaire) at baseline and three months

Apart from clinical disease activity, it also important to take the patient experienced disease load into account. The Rheumatoid Arthritis Disease Activity Index (RADAI) provides an easy to use patients assessment of RA disease activity.

The following secondary outcomes are part of usual care in the treatment of rheumatoid arthritis.

Physical Functioning at baseline and three months

Physical functioning will be measured with the 24-item Dutch version of the Health Assessment Questionnaire (HAQ).

Disease activity at baseline and after three months

Disease activity will be measured with the Disease Activity score (DAS28). The DAS28 is an assessment to RA disease activity as part of usual care. The DAS28 will be collected from the medical file if available at baseline or up to four weeks in advance. Likewise, the DAS28 will be collected at three months (plus or minus a maximum of four weeks) if available.

The outcomes on ‘Medi en Seintje’ only apply to the intervention group.

“Medi en Seintje” outcomes

To assess whether patients have been exposed to serious game “Medi en Seintje” the following outcomes from the application will also be collected:

• Installed on smartphone or tablet

• Number of log-in’s

• Average session time

• Total play-time at one and three months

• Exposure to ‘triggers’ (number of completed triggers for each type of trigger)

• Notifications on/off

“Medi en Seintje” satisfaction at three months

Besides the disease-related outcomes, it also important to know how subjects experience the intervention. After all, the intervention is software and therefore easily adopted to make it more effective or fit user needs better. Hence, ‘Medi en Seintje’ satisfaction will also be assessed at three months.

Study description

Background summary

Country of recruitment: The Netherlands

SUMMARY

Rationale: Effectiveness of pharmacological therapy in inflammatory rheumatic diseases may be limited by inadequate patient adherence to medication. Interventions to improve adherence of DMARDs are therefore necessary to reduce undesirable effects of non-adherence on disease activity, joint damage and overall healthcare costs. Games are increasingly used to address behavioural and psychological factors associated with adherence to medical treatment regimens. Nevertheless, no serious game, where the main goal is providing entertainment, has ever been deployed to subtly and positively influence medication adherence behaviour.

Objective: This study aims to examine the effectiveness of serious game “Medi en Seintje” to improve medication adherence and clinical outcomes in patients with rheumatoid arthritis treated with Disease Modifying Anti-Rheumatic Drugs (DMARDs).

Study design: The effectiveness of this serious game will be assessed in a randomised clinical multicentre trial comparing the serious game intervention to traditional care.

Study population: Adults diagnosed with rheumatoid arthritis treated with Disease Modifying Anti-Rheumatic Drugs

Intervention (if applicable): The intervention group will be asked to install and play a puzzle game on their tablet or mobile phone. Playing the puzzle game is encouraged at the start of the study but otherwise completely voluntary.

Main study parameters/endpoints: The main study parameter is adherence. Primarily this is assessed using the validated Compliance Questionnaire for Rheumatology (CQR). Additionally, a pill count will be performed and the Beliefs About Medicine Questionnaire will be collected. Secondary clinical outcomes are the Health Assessment Questionnaire (HAQ) and the self-reported Rheumatoid Arthritis Disease Activity Index (RADAI). DAS-28 will be gathered if available. Lastly, game experience on the puzzle game will be assessed.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: It has been shown that merely measuring adherence already leads to an increase in adherence. An increase in medication adherence is likely to improve disease outcomes for patients. The intervention itself is voluntary, considered to be fun and no adverse events are to be expected. The burden for patients during a period of three months consists of a total of thirteen extra questionnaires.

Study objective

This study aims to examine the effectiveness of serious game “Medi en Seintje” to improve medication adherence and clinical outcomes in patients with rheumatoid arthritis treated with Disease Modifying Anti-Rheumatic Drugs (DMARDs).

Study design

1 and 3 months

Intervention

Puzzle game 'Medi & Seintje' available on smartphone or tablet. Intervention patients can play at will.

Contacts

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Eligibility criteria

Inclusion criteria

• diagnosis of RA (2010 ARA criteria [21] or clinical judgement by a rheumatologist);

• use at least one DMARD that is dosed weekly or more frequent (in other words: all oral

DMARDs and biological DMARDs injected weekly);

• >18 years;

• sufficient ability to understand Dutch;

• be able to be followed for 3 months (life expectancy);

• in possession of smartphone/tablet.

Exclusion criteria

• cognitive and/or visual limitations that restrain the patient from playing the serious game (as assessed by the healthcare professional);

• assistance in taking drugs (e.g. home care);

• included in another trial.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2019
Enrollment:	220
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL7217
NTR-old	NTR7416
Other	CMO Arnhem - Nijmegen : 2018-4648

Study results