Behavioural interventions to increase test uptake and self-isolation compliance during Covid-19 community test pilots in the Netherlands: four population-level randomised control trials.

Gepubliceerd: 25-03-2021 Laatst bijgewerkt: 18-08-2022

Testing trials: 1. We expect to see a main effect of time on number a) of tests completed b) of persons who get tested c) of tests per person 2. We expect to see a main effect of letter condition. Specifically, we expect that the...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26968

Bron
NTR

Verkorte titel
Behavioral Interventions to increase participation and self-isolation compliance as part of Covid-19 community-wide testing

Aandoening

Covid-19

Ondersteuning

Primaire sponsor: Het Ministerie van Volksgezondheid, Welzijn en Sport
Overige ondersteuning: Het Ministerie van Volksgezondheid, Welzijn en Sport

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Test uptake:
a) DV1: The number of residents, per neighborhood that tested for Covid-19 during the 6-week pilot period.
b) DV2: The number of times a person, per neighborhood got tested for Covid-19 during the 6-week pilot period.

Self-Isolation support and adherence behaviour:
a) DV1: The contact times with a local support service (Bunschoten only)
b) DV2: The number of self-reported times a participant left their residence during the isolation or quarantine period (excluding number of times for medical reasons).
c) DV3: The number of self-reported times a participant received visitors during the isolation or quarantine period (excluding number of times for medical reasons).

Toelichting onderzoek

Achtergrond van het onderzoek

At the start of 2021, the Dutch Ministry of Health, Welfare and Sport (VWS) set out to assess the implementability, scalability, and uses of open-access community-wide Covid-19 testing of asymptomatic individuals in addition to symptomatic individuals. This approach was piloted in collaboration with regional preventative healthcare services (GGD Flevoland and GGDrU) and two local councils (Bunschoten and Dronten) respectively. As part of these pilots we evaluated the effectiveness of behavioural interventions on test uptake and self-isolation compliance in four randomised controlled trials. For participants in all conditions access to regular care remains. Intervention conditions only offer additional care. If residents do not wish to participate in research, they receive care in accordance with national guidelines.

To increase test uptake, we set out to compare two types of invitation and reminder letters. One incorporating behavioural determinants of Covid-19 testing, the other developed by each local council. We also varied ease of access to testing sites by mobility (Bunschoten), locality (Dronten) and availability of drop in (both). We evaluate their effectiveness by assessing (a)symptomatic test uptake during the 6-week period of the community pilot using a randomised controlled design in both test sites. In addition, all residents of Dronten and Bunschoten were invited to complete a short survey to reasons for partaking, after trial completion.

To increase self-isolation compliance, we examined whether active (requesting consent to hand over their phone number) or passive referral (offering the phone number) to a local

wellbeing and support service affected quarantining or self-isolation compliance for (suspected) Covid-19 patients in one site (Bunschoten). In the other site (Dronten), we examined whether a conversation about vs. referral to a self-isolation coping plan identifying barriers for effective self-isolation affected quarantining or self-isolation compliance for (suspected) Covid-19 patients. Both interventions were set out using a randomised controlled design. In addition, the latter site offered a 'Homestay Sack' to patients during the first 3 weeks of the intervention period, containing locally relevant information, a locally sourced gift, a symptom-countdown calendar, and other relevant resources to ease the isolation period. All participants were asked to report on their isolation period in a survey after 10 days.

Doel van het onderzoek

Testing trials:

1. We expect to see a main effect of time on number
a) of tests completed
b) of persons who get tested
c) of tests per person

2. We expect to see a main effect of letter condition. Specifically, we expect that the intervention letter (stressing the importance of testing) compared to the control letter (developed by local council) increase the total number
a) of tests completed
b) of persons who get tested
c) of tests per person

3. We expect to see an interaction effect between the effect of the letters and pilot week, where the difference between intervention and control letters on of
a) of tests completed
b) of persons who get tested
c) of tests per person
changes over time.

4. In Dronten, we expect to see a main effect of test location. To be more precise, we expect that a comparison between two suburban areas Swifterband and Biddinghuizen, where Swifterband (with a local test facility) compared to the Biddinghuizen (without a local test facility) increases the total number
a) of tests completed
b) of persons who get tested
c) of tests per person

5. In Bunschoten, we expect to see an interaction effect between two suburban areas and testweek with alternating presence of a mobile testing facility to show that presence of a mobile testing facility, compared to absence of testing facility increases the total number
a) of tests completed
b) of persons who get tested

c) of tests per person

Self-Isolation support trials:

Bunschoten:
6. We expect to see a difference between referral approaches. Specifically, we expect that active (request to patients to hand phone numbers to the support service, who call) vs passive referral (patients are suggested to call the local support service themselves):
a) Increases the number of conversations between patients and local support service
b) Reduces the number of times patients left the house (excluding for medical needs)
c) Reduces the number of times patients received visitors (excluding for medical needs)

Dronten:
7. We expect to see a main effect of the coping plan referral approach. Specifically, we expect that active walk-through (step-by-step identification of barriers and solutions to the isolation period) vs passive referral (patients are informed of the plan):
a) Reduces the number of times patients left the house (excluding for medical needs)
b) Reduces the number of times patients received visitors (excluding for medical needs).

8. We expect to see a main effect of the Home-Stay bag. We expect to see a trend break between the first and last 3 weeks of the trial period, in
a) Number of times patients left the house (excluding for medical needs)
b) Number of times patients received visitors (excluding for medical needs).
in favour of patients who received the Home stay bag.

Onderzoeksopzet

Isolation adherence: Day 1, Day 5, Day 10.

Onderzoeksproduct en/of interventie

1. RCT 1 Test Dronten -
a) IV1: Locality of test sites, two levels: participants have a local testing facility (Swifterbant, intervention) or not (Biddinghuizen, control).
b) IV2: Invitation and reminder letters, two levels: participants receive a letter written by the local council (control letter) or adjusted to reflect behavioural determinants (intervention).

2. RCT 2 Test Bunschoten -
a) IV1: Locality and mobility of test site using a testbus between two boroughs, two levels: mobile testing facility absent (control), mobile testing facility present (intervention).
b) IV2: Invitation and reminder letters, two levels: participants receive a letter written by the local council (control letter) or adjusted to reflect behavioural determinants (intervention).

3. RCT 3 Self Isolation Dronten -
a) IV1: Coping plans to identify potential barriers during self-isolation, two levels: participants receive an email about the coping plan (control) or discuss the coping plan over the phone (intervention).

b) IV2: A Stay-At-Home bag developed to address determinants of self-isolation, two levels: participants are not offered (control) or are offered the bag (intervention).

4. RCT 4 Self isolation Bunschoten -
a) IV1: Referral to local support services, two levels: participants are informed of the service (control) or called by the service (intervention).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Testing trials: One invitation letter per household was sent to all residents of Dronten and Bunschoten. In the invitation letter, all residents aged 12 and above in Dronten, and aged 6 and above in Bunschoten were invited to partake in the community-wide testing pilot.

Self-Isolation support trials: All residents of Dronten and Bunschoten with a positive test result for covid-19 received care as usual during the six week pilot period, and were invited to partake in the trial. In Bunschoten, close patient contacts at risk of Covid-19, were also invited to partake. Intervention materials developed for the trial only offered to patients aged 16 and above due to legal requirements. In case of patients under the age of 16, intervention materials were offered to the household. Intervention materials were, under those circumstances, also addressed ‘parent(s) of’ the minor in the household. Only participants with insufficient written and spoken knowledge of the Dutch language were unable to participate in the trials.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Testing trials: No exclusion applied to participation, but data was only shared for residents aged 12 and above in Bunschoten. This was because a different set of methods was used to test participants aged 6-12 for Covid-19.
We will only exclude a subject from which the district the subject is living or the condition the subject is assigned to is missing. If the condition a subject belongs to, or the district a subject lives in is missing, this subject will be excluded from the analysis.

Self-Isolation support trials: No exclusions were applied to receive self-isolation care as usual.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	08-02-2021
Aantal proefpersonen:	25644
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	25-03-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9365
Ander register	VWS, UvA, RIVM : 2021-PML-13061

Resultaten

Samenvatting resultaten
N/A