Author's response to reviews

Title: Effectiveness of an online group course for adolescents and young adults with depressive symptoms: Protocol of a randomised controlled trial

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Author's response to reviews: see over
Cover letter
‘Effeciveness of an online groups course for adolescents and young adults with depressive symptoms: Protocol of a randomized controlled trial’

Comment A1) On the second page, first paragraph under Background, the 6.7% is unclear. Is this incidence?
Answer: This percentage refers to the 12-months prevalence. This information is inserted in the first paragraph.

Comment A2) It doesn’t really make sense to use a precise figure for the polulation. If the number is used, it should be couched in a phrase such as ‘One study found that...’.
Answer: This quote is inserted in the first paragraph.

Comment A3) The reference 20% comes from a reference that is 15 years old. Is there an updated reference?
Answer: Two (updated) references are inserted in the first paragraph.

Comment B1) On the fourth page, under Randomization, knowing that the blocks are of size two (especially in an unblinded trial) can subconsciously cause an investigator to delay entering someone in order to affect the assignment. It would have been better to either randomly change the block size or keep it hidden.
Answer: The researcher is not involved in the online randomization process and has no influence on it. The randomization will take place online in an automated way if one of the course facilitators indicates that someone is suitable for the course by clicking on a button. The course facilitators are unaware of the block size and strata used. Also they are not aware of the outcomes of the other participants being randomized by other course facilitators. So it will be very hard for individual course facilitators to predict what the next outcome will be.

Comment B2) In the same paragraph, it is said that if a participant declines, a tailored referral will be provided. Can a participant decline after randomization? If so, how will the analysis be done (with or without this participant)?
Answer: The medical ethical committee insists that if someone chooses to decline to participate, even after randomization, this should always be possible. These participants will be included in the analyses (the intention-to-treat principle will be applied here). In the analysis paragraph some information is inserted about this procedure.

Comment C) On the fifth page, a description of what those assigned to control will do and how they will be contacted for the repeat assessment would be helpful.
Answer: The control group will be placed on a waiting list (3 months). This group will not receive an intervention. All participants in the study, also the individuals on the waiting list, will be contacted by e-mail for the repeat assessment in an automated way.
Comment D) On the seventh page, there is no mention of any interim monitoring. Despite excluding those deemed prone to suicide, there might still be some suicide attempts. Is there any safety concern that would suggest interim monitoring could be important? Also, what if the outcome trends in the unexpected direction? Is this a safety concern?

Answer:
No interim monitoring takes place. The high risk group is excluded by the screenings procedure described in Methods (sample). Further safety measures are as follows: 1) in the informed consent letter all applicants (wait listed and experimental group) are pointed out to seek help by the general practitioner when the complaints are growing worse. 2) On the website www.griopejdip.nl a list of addresses and telephonenumbers of helping agencies are published. 3) Also a protocol for the courseleaders is formulated for cases of emergency.

Comment E) Pagination should be included.
Answer: pagination is inserted.