Help in hand after traumatic events: a randomized controlled trial in health care professionals on the efficacy, usability, and user satisfaction of a self-help app to reduce trauma-related symptoms

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ABSTRACT

Background: Despite the fact that many people are affected by trauma and suffer from posttraumatic stress symptoms (PTSS), there is a lack of easy-accessible interventions to self-manage these symptoms. Mobile apps may deliver low-intensity self-help to reduce trauma-related symptoms and empower individuals following trauma, such as high-risk professionals who are regularly exposed to potentially traumatic events. In this randomized controlled trial, we examined the efficacy, and evaluated the usability and user satisfaction of the app ‘SUPPORT Coach’ as a self-help tool to reduce trauma-related symptoms.

Methods: Health care professionals (e.g. nurses, physicians, paramedics and ambulance drivers) completed an online screening on PTSS (T0). They were randomized when at least one PTSS was reported, either to the intervention (1 month unlimited access to SUPPORT Coach) or control condition (no access to SUPPORT Coach). Self-reported PTSS, negative trauma-related cognitions, psychological resilience, and social support were assessed online at baseline (T1), post-condition (T2), and 1 month follow-up (T3).

Results: Of the 1175 participants screened, 287 (24.4%) indicated at least one posttraumatic stress symptom and were randomized. The majority of intervention condition participants (83%, n = 103) used SUPPORT Coach; they were slightly to moderately satisfied with the app. There was no significant group differences in change in PTSS and social support after one-month app usage. However, the intervention condition showed a greater decline in negative trauma-related cognitions at T2 and T3, and a larger increase in psychological resilience at T3 than the control condition.

Conclusions: SUPPORT Coach without guidance could potentially provide easy-accessible self-help to diminish negative trauma-related cognitions, and strengthen resilience in coping with adversities. However, since the attrition rate was substantially higher in the intervention than in control condition, our findings should be interpreted with caution and warrant replication.

AJuda a la mano después de eventos traumáticos: un ensayo controlado en profesionales de la salud sobre la eficacia, usabilidad y satisfacción de una aplicación de autoayuda para reducir síntomas relacionados con el trauma

Antecedentes: Pese al hecho de que muchas personas son afectadas por traumas y sufren de síntomas de estrés postraumático (PTSS por sus siglas en inglés) existe una carencia de intervenciones fácilmente accesibles para auto-manear estos síntomas. Las aplicaciones móviles pueden entregar autoayuda de baja intensidad para reducir los síntomas relacionados con el trauma y empoderar individuos posterior a un trauma, tales como en profesionales de alto riesgo que están regularmente expuestos a eventos potencialmente traumáticos. En este ensayo controlado bajo condiciones aleatorias examinamos la eficacia, y evaluamos la usabilidad y satisfacción de la aplicación ‘SUPPORT Coach’ como una herramienta de autoayuda para reducir síntomas relacionados con el trauma.

Métodos: Profesionales de atención en salud (como enfermeras, médicos, paramédicos y conductores de ambulancia) completaron un tamizaje online de PTSS (T0). Fueron randomizados cuando al menos un PTSS fue reportado, ya sea a la intervención (1 mes de acceso ilimitado a SUPPORT Coach) o a control (sin acceso a la aplicación). Se evaluó el auto-reporte de PTSS, cogniciones negativas relacionadas al trauma, resiliencia psicológica y apoyo social basalemente (T1), post condición (T2) y un seguimiento al mes de la intervención (T3).

Resultados: de los 1175 participantes tamizados, 287 (24.4%) indicaron al menos un síntoma de estrés postraumático y fueron randomizados. La mayoría de los participantes del grupo de intervención usaron SUPPORT Coach (83% n=103), y se encontraron de leve a moderadamente satisfechos con la aplicación. No hubo diferencia significativa en los grupos en PTSS y en apoyo social después de un mes de haber utilizado la aplicación. Sin embargo, la tasa de attrition fue considerablemente más alta en el grupo de intervención que en el control, lo que debe interpretarse con cautela y requerir replicación.
1. Introduction

Around 70% of the worldwide general population will experience a potentially traumatic event (PTE) during their life (Benjet et al., 2016). While only a small minority suffers from full-blown posttraumatic stress disorder (PTSD) after a PTE (Kessler et al., 2017), many will develop posttraumatic stress symptoms (PTSS) (Birkeland, Hansen, Blix, Solberg, & Heir, 2017; Brancu et al., 2016). Although PTSS decline gradually in the majority of people and are less impairing than full-blown PTSD, they nevertheless cause distress and are associated with depression, alcohol use, and limitations in occupational and social functioning (Cukor, Wyka, Jayasinghe, & Difede, 2010; Marshall et al., 2001). Moreover, individuals with PTSS are at increased risk of developing (delayed) PTSD, especially after experiencing subsequent PTEs or other stressors (Smid, Moorren, van der Mast, Gersons, & Kleber, 2009). This heightened chance to develop (delayed) PTSD may particularly apply to high-risk professions such as health care professionals (HCPs), who are regularly exposed to work-related trauma (De Boer et al., 2011; van Steijn et al., 2019). Prevalence rates for probable PTSD in HCPs including nurses, doctors and ambulance personnel vary between 8% and 29 (Petrie et al., 2018; Robertson & Perry, 2010), and PTSS ranges up to 30% (De Boer et al., 2011).

Despite the high prevalence, negative consequences and potential worsening of PTSS, there is a lack of easy-accessible interventions to reduce these symptoms (Kuhn et al., 2017; Marshall et al., 2001; Olff, 2015). Smartphone applications (apps) offer possibilities in delivering low-intensity interventions to empower trauma-exposed individuals, and self-manage trauma-related outcomes (Kuhn et al., 2018; Olff, 2015).

Previous studies have already demonstrated the efficacy of self-help apps in reducing psychological symptoms such as anxiety (Firth et al., 2017), depressive symptoms and work absence (Binrey, Gunn, Russell, & Ary, 2016), and stress, substance abuse and depression (Donker et al., 2013). Regarding PTSS, the most well-known app is PTSD Coach, developed by the Veterans Affairs National Centre for PTSD in the USA (U.S.) (Kuhn et al., 2014). PTSD Coach was designed to self-manage trauma-related symptoms, and contains psychoeducation, a self-assessment, and exercises based on cognitive behavioural therapy (CBT) to cope with PTSD.

Previous PTSD Coach studies in individuals with severe levels of PTSS (i.e. probable full-blown PTSD) demonstrated moderate to high levels of perceived helpfulness of the app (Kuhn et al., 2014), and showed that usage of PTSD Coach led to improvements in PTSD, depressive symptoms, and psychosocial functioning (Kuhn et al., 2017). Since PTSD Coach offers strategies to cope with distressing thoughts, social network building, and empowering exercises, it may have beneficial effects in reducing trauma-related cognitions, and enhancing social support and psychological resilience as well.
These factors play a crucial role in the response to trauma, as negative trauma-related cognitions (e.g., negative thoughts about self ‘I am incompetent’, others ‘people are untrustworthy’ and the world ‘the world is an unsafe place’) and lack of perceived social support are associated with the presence of PTSS (Brewin, Andrews, & Valentine, 2000). On the positive side of the spectrum, psychological resilience (van der Meer et al., 2018), seems to be associated with the presence of less PTSS (Bonanno, Brewin, Kaniasty, & Greca, 2010; Bonanno, Field, Kovacevic, & Kaltman, 2002). Up to now, it is unclear if the app is effective in individuals with low levels of PTSS and if it has beneficial effects on negative cognitions, social support, and resilience.

Therefore, we examined the efficacy of the Dutch equivalent of U.S. PTSD Coach, called SUPPORT Coach, as a self-help app in reducing PTSS, negative trauma-related cognitions, lack of social support, and enhancing psychological resilience in HCPs with low levels of PTSS (i.e. one or more posttraumatic stress symptom) in a randomized controlled trial (RCT). Additionally, we evaluated the usability and user satisfaction of the app.

2. Methods

2.1. Participants and study overview

Researchers informed multiple hospitals and ambulance regions in the Netherlands about the SUPPORT Coach study and asked permission for the recruitment of their employees. Researchers visited 15 hospital departments and eight ambulance regions who gave permission for recruitment, and informed HCPs (e.g., hospital employees such as nurses and physicians, and paramedics and ambulance drivers) about the SUPPORT Coach study. Researchers explained the study aim, procedures, and eligibility criteria (i.e., having a smartphone or tablet, age ≥18, and mastery of the Dutch language). If HCPs were willing to participate, they were asked to sign the informed consent. There was no compensation for study participation. After providing written informed consent, participants (n = 1175) received a link to the online screening (T0) that consisted of the primary care PTSD Screen for DSM-5 (PC-PTSD-5) (Bakker, van der Meer, & Olff, 2014; Prins et al., 2016) to indicate if they had experienced a PTE. If so, five items were administered about the presence (0 = no, 1 = yes) of PTSS during the past month. A highly sensitive cut-off point of ≥1 on the PC-PTSD-5 was chosen, with a previously reported sensitivity and specificity for PTSD diagnosis of 99% and 67%, respectively, in a convenience sample of American veterans (Prins et al., 2016). Participants scoring ≥1 were randomized to the intervention (1 month unlimited access to the app) or control condition (no access to the app). All participants could use their own (mental) health care as usual if applicable. Assessments were scheduled at T1 (baseline), T2 (directly post-condition), and T3 (1 month follow-up) (Figure 1). For details on all administered measures, see supplementary methods.

2.2. Procedure and assessments

Data were collected between January 2015 and March 2016. The study was approved by the

Figure 1. Schematic overview of study design and measurements. PC-PTSD-5, Primary Care PTSD Screen for DSM-5; LEC-5, Life Events Checklist for DSM-5; PCL-5, PTSD checklist for DSM-5; PTCI, Peritraumatic Cognitions Inventory; RES, Resilience Evaluation Scale; SSL-6, Social Support List.
Institutional Review Board of the Academic Medical Centre, Amsterdam, the Netherlands. Good Clinical Practice guidelines were followed during all study procedures, including informed consent. The randomization was carried out by a researcher with no role in data collection via ALEA Clinical (version 2, FormsVision, Abcoude, The Netherlands) in a block-design using random block sizes (maximum block size 6), and stratified by ambulance region or hospital department. After randomization, participants received the T1 assessment by email. If T1 was not completed within 14 days, participants were considered drop-out, and not invited to complete T2 and T3. Participants were invited to complete T3 regardless of whether they completed T2. All self-report assessments (see supplementary methods) were administered online via a secured web-based app.

2.3. Intervention

The content of SUPPORT Coach is derived from U.S. PTSD Coach. The overall look and feel of SUPPORT Coach were modified to make it bright and clear, using simple icons to help users navigate through the app. The U.S. PTSD Coach was originally developed for veterans and contained specific information and contact details of health care institutions aimed at U.S. veterans. The ‘Information’ and ‘Support’ sections within SUPPORT Coach were modified to make the app applicable to a more general trauma-exposed population. For example, generic information about PTSD without focusing on veterans is given, and several health care institutions for a broad range of trauma-exposed populations (e.g. civilians, high-risk employees, refugees) are provided. Further, the ‘Manage symptoms’ section was divided into the subsections ‘Tools’ and ‘Symptoms’, a ‘Calendar’ feature was added, and the ‘Self-test’ and ‘Information’ sections are conform DSM-5 (Kuhn et al., 2018). SUPPORT Coach consists of five sections. The ‘Information’ section (1) offers psychoeducation about trauma, PTSS, and professional care. The ‘Find support’ section (2) facilitates contact with the user’s personal network and professional care. The ‘Self-test’ section (3) contains the PTSD checklist for DSM-5 (PCL-5) to assess and monitor PTSS (severity). The ‘Calendar’ section (4) allows users to schedule self-tests, exercises, and activities. The heart of the app is the ‘Manage Symptoms’ section (5), containing various CBT-based exercises to self-manage PTSS (e.g. progressive muscle relaxation, change cognitive perspective, and pleasant events with others). Each participant in the intervention condition who completed T1 received a download link and a unique username and password via email to install SUPPORT Coach on their own smartphone or tablet (iOS and/or Android systems). The SUPPORT Coach was not publicly available in the Apple store or Google Play store during the trial. Participants received no specific instructions on how to use the app (i.e. stand-alone usage) in order to mimic the real world as close as possible. Participants were called after approximately 5 days to check for installation issues, and received a reminder by email after 7 days if the installation was not completed. SUPPORT Coach automatically became inactive 1 month (at T2) after receiving the login information. Participants were not excluded if they did not install the app. Individual usage patterns of the SUPPORT Coach were tracked via a back-office system specifically developed for this study. The following objective usage data were gathered: number of times the app was used, number of completed self-tests and performed app exercises, and time spent in app (each time the app was opened).

2.4. Statistical analyses

Analyses were performed using IBM SPSS Statistics 24. Baseline differences between conditions and between T1, T2 and T3 completers (participants who completed PCL-5) vs. non-completers (not completed PCL-5) were examined using Mann–Whitney U tests for non-normally distributed variables, and χ² and Fisher’s exact tests for categorical variables. Descriptive statistics were used to describe the participant flow, usability, and user satisfaction. Due to a technical error, total minutes of active app usage above 1 min were not reliably registered in a subgroup of participants, so only a dichotomous measure during the entire intervention period (app usage ≤ or ≥1 minute) is presented.

To determine changes in outcome variables at T2 and T3 and to control for baseline levels of these variables, delta (Δ) scores for the PCL-5, PTCI, RES and SSL-6 were computed by subtracting the total T1 scores from the total T2 and T3 scores, respectively. The Δ scores and total scores on all outcome variables at all assessments (T1, T2 and T3) were non-normally distributed. As multiple transformations on the data (Field, 2009) did not yield normally distributed variables, non-parametric test were applied. To assess whether change in the outcome variables differed between the two conditions and to control for baseline levels of the outcome variables, Mann–Whitney U tests (non-parametric test) were performed using the Δ scores. In this test, Δ scores are compared in the group of participants that completed both T1 and T2, and both T1 and T3, respectively. These were followed by Wilcoxon signed-rank tests (non-parametric test) to examine whether the PCL-5, PTCI, RES and SSL-6 total scores significantly changed in the two conditions separately from T1 to T2, and from T1 to T3. In this test, Δ scores are
compared in the group of participants that completed both T1 and T2, and both T1 and T3, respectively. For Mann–Whitney U test and Wilcoxon signed-rank test, effect size $r$ was calculated by dividing the test statistic ($Z$) by the square root of the number of observations $(.01 = \text{small effect}, .0.3 = \text{medium effect}, .0.5 = \text{large effect})$ (Field, 2009). Spearman rank correlations ($r_s$) were calculated between number of performed SUPPORT Coach exercises, all baseline outcome measures, and T2-T1 and T3-T1 $\Delta$ total scores.

In all models, $p < .05$ was considered statistically significant. Post-hoc tests of the four outcome measures in separate conditions were corrected with false discovery rate correction (Benjamini & Hochberg, 1995). Power analysis using NQuery Advisor 7.0 determined that to demonstrate a difference of at least 5 points (Wortmann et al., 2016) on the PCL-5 (SD of 12.9, estimated from a previous study in a comparable population) between conditions at T2 (equivalent to a medium effect size of 0.39), 106 participants in each condition were required (power 80%; two group t-test with a 0.05 two-sided significance level). To allow for 23% attrition over 1 month (Mouthaan et al., 2013), 138 participants were needed in each condition.

3. Results

3.1. Participant flow and characteristics

A total of 1175 participants completed the online screening of whom 76.2% ($n = 895$) indicated that they ever had experienced a PTE and 287 (24.4% of the 1175 and 32.1% of the 895 participants) had a PC-PTSD-5 total score of $\geq 1$ and were randomized (Figure 2). There were significantly more completers in the control condition than in the intervention condition at all assessments, $\chi^2(1) = 4.035, p = .045$ at T1, $\chi^2(1) = 12.869, p = .000$ at T2, and $\chi^2(1) = 8.703, p = .003$ at T3. Missing values analysis (Little’s test) indicated that missing data were missing completely at random (MCAR), $\chi^2(84) = 104.466, p = .065$. T1 drop-outs did not significantly differ from T1 completers in terms of PC-PTSD-5 total score, but were younger, more often hospital employee than ambulance worker, and more frequently female (Table 1). At T2 and T3, non-completers did not significantly differ from completers at the respective time points on any baseline demographic or clinical characteristic, except that non-completers were younger than completers at both assessments (Table 1). There were no baseline differences between conditions in demographic and clinical characteristics (Table 2), and no differences at T1, T2 and T3 in current or past treatment for psychological problems, and the number of experienced PTEs.

3.2. Usage and evaluation of the SUPPORT Coach

Of the 124 intervention condition participants who received SUPPORT Coach login details, 110 (88.7%) downloaded and logged in to the app, and 103 (83%) used the app. The 103 participants opened the app 9 times on average (SD = 6.55, range = 1–43), performed 27.4 exercises on average (adding all performed exercises, including the same type performed multiple times, Mdn = 2, SD = 134.8, range 0–1394), and 82 (79.6%) participants completed the self-test within SUPPORT Coach at least once. More PTSS and negative trauma-related cognitions, and less psychological resilience at T1 were related to more performed SUPPORT Coach exercises, and less psychological resilience at T1 were related to more performed SUPPORT Coach exercises between T1 and T2 ($r_s = .205, p < .05, r_s = .271, p < .01$, and $r_s = -.304, p < .01$, respectively). Number of performed exercises was not related with other baseline clinical characteristics or T2-T1 and T3-T1 $\Delta$ total scores on any outcome measure. Of the 83 participants who used the app and completed T2, 68 (81.9%) reported that the app was easy to use, and 51 (62.2%) would recommend it to others. Table 3 provides an overview of the perceived helpfulness of and satisfaction with the app.

3.3. Efficacy of the SUPPORT Coach

3.3.1. Primary outcome – PTSD symptoms

$\Delta$ PCL-5 total (T2-T1 and T3-T1) scores did not differ between conditions (Table 4). Analyses for the conditions separately showed that total PCL-5 scores (PTSS) significantly declined from T1 to T2 and from T1 to T3 in both conditions (Table 5).

3.3.2. Secondary outcomes – negative cognitions, psychological resilience, social support

$\Delta$ PTCI total scores significantly differed between conditions; the intervention condition showed a greater decline in PTCI total score (negative cognitions) from T1 to T2 and T1 to T3 compared to the control condition (Table 4). Analyses for the conditions separately showed that PTCI total scores significantly declined from T1 to T2 and from T1 to T3 in the intervention, but not in the control condition (Table 5). $\Delta$ RES total scores significantly differed between conditions; the intervention condition showed a greater increase in RES total scores (psychological resilience) from T1 to T3 (not from T1 to T2), compared to the control condition (Table 4). Analyses for the conditions separately showed that RES total scores significantly increased from T1 to T2, and from T1 to T3 in the intervention, but not in the control condition (Table 5). $\Delta$ SLL-6 total scores did not differ between conditions (Table 4). Analyses for the conditions separately showed that SLL-6 total scores.
Table 1. Significant differences in demographic characteristics between drop-outs and completers on T1, T2, and T3 for the total group.

| Assessment | Non-completer (n = 88) | Completer (n = 199) | Test Value | p     |
|------------|------------------------|---------------------|------------|-------|
| T2         | All                    |                      |            |       |
| Age, mean (SD) | 39.6 (10.5)           | 44.5 (9.2)          | U = 6257.00 | .000  |
| Gender, n (%)  |                        |                     |            |       |
| Female      | 21 (75)                | 137 (52.9)          | χ²(1) = 4.989 | .026  |
| Male        | 7 (25)                 | 122 (47.1)          |            |       |
| T3         | All                    |                      |            |       |
| Age, mean (SD) | 40.77 (10.5)          | 44.47 (9.19)        | U = 7401.00 | .002  |

Note: Reasons for drop-out were unknown in the vast majority of cases. Eleven participants explicitly stated the reason for termination of their participation, the main reasons were lack of time, interest and motivation. Participants who dropped-out at the T1 assessment were excluded from the further trial (i.e. did not receive login details of app upon randomization to intervention condition) and were not invited for the T2 and T3 assessment.

Table 1. Significant differences in demographic characteristics between drop-outs and completers on T1, T2, and T3 for the total group.

| Assessment | Total group | Drop-out (n = 28) | Completer (n = 259) | Test Value | p   |
|------------|-------------|-------------------|---------------------|------------|-----|
| T1         |             |                   |                     |            |     |
| Age, mean (SD) | 39.4 (10.8) | 43.4 (9.7)        | U = 2792.500       | .046       |
| Job, n (%) |             |                   |                     |            |     |
| Ambulance  | 13 (46.1)   | 171 (66)          | χ²(1) = 4.217       | .040       |
| Hospital   | 15 (53.6)   | 88 (34)           |                     |            |     |
| Gender, n (%) |          |                   |                     |            |     |
| Female     | 21 (75)     | 137 (52.9)        | χ²(1) = 4.989       | .026       |
| Male       | 7 (25)      | 122 (47.1)        |                     |            |     |
| T2 assessment |           |                   |                     |            |     |
| Age, mean (SD) | 39.6 (10.5) | 44.5 (9.2)        | U = 6257.00       | .000       |
| T3 assessment |           |                   |                     |            |     |
| Age, mean (SD) | 40.77 (10.5)| 44.47 (9.19)     | U = 7401.00       | .002       |

*At T0, 55% was ambulance worker and 45% was hospital employee. At T1, 66% was ambulance worker and 34% was hospital employee.
score (perceived lack of social support) significantly declined from T1 to T3, but not from T1 to T2, in the intervention condition. In the control condition, SLL-6 scores not significantly declined from T1 to T2 or T1 to T3 (Table 5).

4. Discussion

This is one of the first studies that examined the efficacy, usability and user satisfaction of a stand-alone self-help app for trauma-related symptoms in HCPs with PTSS. There was no effect of the app on PTSS and social support. However, participants in the intervention condition showed a greater decline in negative trauma-related cognitions and larger increase in psychological resilience compared to individuals in the control group who did not use the app. Also, results showed that the large majority of participants used the app and found the app easy to use. Perceived helpfulness was on average modest. The beneficial effects of SUPPORT Coach on negative trauma-related cognitions and psychological resilience may be attributed to specific app exercises providing strategies to cope with distressing thoughts and fostering resilience, and to normalization of cognitive and emotional reactions after trauma through the psycho-education section within the app (Cernvall, Sveen, Bergh Johannesson, & Arnberg, 2018). To note, two-thirds of participants indicated that more negative trauma-related cognitions as measured by the PTCI prior to a PTE (Bryant & Guthrie, 2010). Interestingly, multiple studies have found that more negative trauma-related cognitions as measured by the PTCI prior to a PTE (Bryant & Guthrie, 2010) and soon after a PTE (O’Donnell, Elliott, Wolfgang, & Creamer, 2007; Shahar, Noyman, Donnell, Elliott, & Creamer, 2013) predicts

Table 2. Baseline (T1) demographic and clinical characteristics.

| Demographic Characteristics | Total group (n = 259) | Control group (n = 135) | Intervention group (n = 124) | Test-value | p |
|-----------------------------|----------------------|------------------------|-----------------------------|------------|---|
| Age, mean (SD)              | 43.37 (9.72)         | 43.81 (9.97)           | 42.90 (9.4)                 | U = 7871.00 | .007 |
| Female, n (%)*              | 137 (52.9)           | 70 (51.1)              | 67 (48.9)                   | χ2(1) = .123 | .725 |
| Education, n (%)            | 4 (1.5)              | 3 (2.2)                | 1 (0.8)                     | F(3) = 1.973 | .586 |
| Low                         | 97 (37.5)            | 54 (40)                | 43 (34.7)                   |            |    |
| Middle                      | 151 (58.3)           | 74 (54.8)              | 77 (62.1)                   |            |    |
| High                        | 7 (2.7)              | 4 (3)                  | 3 (2.4)                     |            |    |
| Current work hours, n (%)   | 0                    | 1 (0.8)                |                             |            |    |
| 1-20 hours                  | 10 (3.9)             | 6 (4.4)                | 4 (3.2)                     |            |    |
| >20 hours                   | 246 (95.0)           | 127 (94.1)             | 119 (96)                    |            |    |
| Job, n (%)                  | 3 (2.4)              |                       |                             |            |    |
| Ambulance                   | 171 (66.0)           | 88 (65.2)              | 83 (66.9)                   |            |    |
| Hospital                    | 88 (34.0)            | 47 (34.8)              | 41 (33.1)                   |            |    |
| Ethnicity, n (%)            | 251 (96.9)           | 129 (95.6)             | 122 (98.4)                  | χ2(1) = 1.731 | .188 |
| Dutch                       | 8 (3.1)              | 6 (4.4)                | 2 (1.6)                     |            |    |
| Marital status, n (%)       | 147 (56.8)           | 75 (55.6)              | 72 (58.1)                   | F(5) = 7.173 | .200 |
| Married                     | 54 (20.8)            | 27 (20)                | 27 (21.8)                   |            |    |
| Relationship, no cohabitation | 12 (4.6)           | 9 (6.7)                | 3 (2.4)                     |            |    |
| Single                      | 27 (10.4)            | 15 (11.1)              | 12 (9.7)                    |            |    |
| Widow(er)                   | 15 (5.8)             | 9 (6.7)                | 6 (4.8)                     |            |    |
| Other                       | 4 (1.5)              | 0 (0)                  | 4 (3.2)                     |            |    |
| Top 4 most common trauma, n (%) | 12 (4.6)           | 8 (5.9)                | 4 (3.2)                     | χ2(15) = 18.726 | .226 |
| Life-threatening illness or injury | 12 (4.6)           | 8 (5.9)                | 4 (3.2)                     |            |    |
| Serious accident            | 12 (4.6)             | 5 (3.7)                | 7 (5.6)                     |            |    |
| Sudden violent death        | 16 (6.2)             | 7 (5.3)                | 9 (7.3)                     |            |    |
| Severe human suffering      | 36 (13.9)            | 23 (17)                | 13 (10.5)                   |            |    |
| Clinical characteristics    |                      |                       |                             |            |    |
| Currently receiving treatment for psychological complaints (yes), n (%) | 34 (13.1)         | 18 (13.3)              | 16 (12.9)                   | χ2(1) = .010 | .918 |
| Past treatment for psychological complaints (yes), n (%) | 141 (54.4)        | 69 (51.1)              | 72 (58.1)                   | χ2(1) = 1.260 | .262 |
| Indication PTSD PCL-5 cut-off ≥ 31 | 23 (8.9)         | 15 (11.1)              | 8 (6.5)                     | χ2(1) = 1.374 | .226 |
| Indication PTSD PCL-5 diag. (Int.) | 21 (8.1)        | 13 (9.6)               | 8 (6.5)                     | χ2(1) = .876 | .349 |
| PCL-5 total score, mean (SD) | 12.44 (11.15)    | 12.38 (11.49)          | 12.52 (10.81)               | U = 8120.500 | .678 |
| PTCI total score            | 44.66 (28.74)^a     | 63.17 (27.63)^b        | 66.29 (29.94)^c             | U = 7610.50 | .393 |
| RES, mean, (SD)             | 24.63 (4.84)         | 24.92 (4.75)           | 24.32 (4.93)                | U = 7686.00 | .255 |
| SSL, mean (SD)              | 8.65 (2.98)^a       | 8.83 (3.05)^b          | 8.46 (2.91)^c               | U = 7380.500 | .283 |

U: Mann–Whitney U tests (non-normally distributed continuous variables); χ2: chi-square tests (categorical variables with cell frequencies ≥5); F: Fisher’s exact tests (categorical variables with cell frequencies <5).

*PTCI scores: total group n = 255; control group n = 133; intervention group n = 122.

SSL scores: total group n = 253; control group n = 131; intervention group n = 122.
(higher levels of) PTSS later on. The beneficial effects of SUPPORT Coach are promising in terms of preventing and reducing PTSS. In order to examine this potential preventive effect, future studies are warranted and should include pre- and early post-trauma assessments, as well as long-term follow-ups, and encourage app usage upon novel trauma occurrence. Also, since high-risk professionals such as HCPs have stressful jobs and are routinely exposed to stressful events and traumatized individuals (Cieslak et al., 2014), attention should be paid to work-related stress, burn-out and secondary traumatic stress (STS) (Klein & Westphal, 2011). Studies into the role of apps and population-specific needs regarding such apps in diminishing these negative mental health outcomes are warranted. In addition, future research should examine the potential effect of SUPPORT Coach in facilitating referral to professional care if necessary (Miner et al., 2016), as an adjunctive tool during psychotherapy (Kuhn et al., 2018), and as a supportive tool after treatment to prevent and monitor symptom occurrence.

Of notice, the attrition in our trial poses a threat to the validity of our study since missing data reduces statistical power and increases the chance of biased estimates (Little et al., 2012). The attrition rates were higher in the intervention than in the control condition at all assessments. This may have led to either an overestimation (e.g. participants who perceived the app as helpful could have been more inclined to complete the assessments) or underestimation (e.g. participants may have dropped out because they assumed the app would not be helpful or they felt no need for an intervention) of the true effects of the app. Although our missing data were completely missing at random (i.e. not related to any study variable) indicating no selective attrition, our results regarding the efficacy of and satisfaction with SUPPORT Coach still may be biased. Thus, our results should be interpreted with caution and warrant replication. Missing data is a common problem in clinical trials in general (Little et al., 2012), and in web-based intervention studies in particular wherein relatively high attrition rates repeatedly have been found (Beatty & Binnion, 2016; Christensen, Griffiths, & Farrer, 2009), with percentages comparable to our study. In our study, all assessments were administered online, without face-to-face contact, which may have increased attrition. It is important to address reasons for missing data, possibly particularly in online trials, because it diminishes the ability to draw causal, firm conclusions from these trials. Several analysis methods exist to handle missing data, but they do not offer perfect solutions to ensure the validity of a study. Therefore, the occurrence of missing data should be minimized in the first place (Little et al., 2012). The following suggestions may minimize missing data in general, but may even more

| SUPPORT Coach survey item | M (SD) | Endorsed moderately or greater (%) |
|---------------------------|--------|-----------------------------------|
| Helping me learn about my symptoms of PTSD | 2.27 (1.17) | 67.5 |
| Helping me learn about treatments for PTSD | 1.76 (1.13) | 55.4 |
| Helping me find effective ways of managing my symptoms | 1.40 (1.15) | 39.8 |
| Helping me feel more comfortable in seeking support | 1.07 (1.06) | 33.7 |
| Helping me feel there is something I can do about my PTSD | 1.90 (1.19) | 57.8 |
| Helping me track my symptoms | 1.53 (1.23) | 49.4 |
| Helping me know when I’m doing better or when I’m doing worse | 1.30 (1.25) | 43.4 |
| Increasing my access to additional resources | 1.72 (1.26) | 54.2 |
| Providing practical solutions to the problems I experience | 1.49 (1.20) | 44.6 |
| Helping me overcome the stigma of seeking mental health services | 1.16 (1.15) | 39.8 |
| Helping me better understand what I have been experiencing | 1.42 (1.16) | 41.0 |
| Enhancing my knowledge of PTSD | 1.70 (1.18) | 53.0 |
| Helping clarify some of the myths about PTSD | 1.31 (1.10) | 43.0 |
| Providing a way for me to talk about what I have been experiencing | 0.99 (1.10) | 36.1 |
| Overall, how satisfied are you with the SUPPORT Coach? | 1.83 (1.21) | 59.0 |

Answer categories on SUPPORT Survey: 0 = not at all: 1 = slightly: 2 = moderately: 3 = very: 4 = extremely.

*n = total number of participants who used the app and completed SUPPORT Coach survey.

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**Table 3.** Perceived helpfulness of and satisfaction with SUPPORT Coach.

**Table 4.** Differences in Δ PCL-5, PTCI, RES and SSL-6 total scores from baseline to post-condition, and from baseline to one-month follow-up between conditions (Mann–Whitney U test and effect sizes).
so apply to (online) self-help studies in which the modest level of dysfunctioning of participants requires extra careful consideration of the following topics: adequately inform the participants about the importance of completing the assessments regardless of whether they ‘used’ the studied intervention; incorporate some form of (face-to-face) contact during the assessments; provide a (monetary) incentive to participants for completing their assessments; limit the number of questionnaires and therefore the burden of the assessments; and examine the reasons for dropout during the study, to use this information to minimize further drop-outs (Little et al., 2012).

The absence of an effect of SUPPORT Coach on PTSS and lack of social support is in line with a U.S. community sample pilot study that did not find an effect of one-month U.S. PTSD Coach usage on PTSS (Miner et al., 2016). Interestingly, another RCT in U.S. trauma survivors demonstrated that 3-months usage of PTSD Coach did lead to a beneficial effect on PTSS (Kuhn et al., 2017). This finding suggests that having or using the app for a longer time may lead to more beneficial effects. Importantly, in both U.S. studies, participants had much higher levels of PTSS (mean PCL-5 total score of approximately 60) than participants in our study (mean PCL-5 total score of 12). Our study population had a general low level of PTSS, with arguably less psychological resilience at baseline were all related to more performed SUPPORT Coach exercises, which could suggest that the more individuals suffered from trauma-related symptoms, the more they used the app.

SUPPORT Coach was rated slightly to moderately helpful in dealing with PTSS. Six out of 15 items on the helpfulness of and satisfaction with SUPPORT Coach were rated as moderately or greater by more than half of the participants. Our results are exactly in line with the results of a study on one-month stand-alone usage of the Swedish PTSD Coach in individuals with moderate levels of PTSS (PCL-5 total score of 36.89 at baseline) (Cernvall et al., 2018). However, our ratings are lower than the ratings in an U.S. study in which veterans rated the U.S. PTSD Coach moderately to very helpful (on all 15 items) (Kuhn et al., 2014). The six items that were endorsed as at least moderate in our study reflected evaluations of helpfulness of psychoeducation on PTSS delivered within the app (e.g. ‘Helping me learn about my symptoms of PTSD’, ‘Helping me find effective ways of managing my symptoms’, ‘Providing practical solutions to the problems I experience’). Our lower ratings of these specific items could be partly explained by the fact that our participants had less PTSS than the U.S. veterans (who suffered from full-blown PTSD), and therefore possibly did not feel the need to self-manage their PTSS, used less self-management tools within the app, or did not experience a significant improvement in PTSS after using these

## Table 5. PCL-5, PTCI, RES and SSL-6 total scores from baseline to post-condition, and from baseline to one-month follow-up for the two conditions separately (Wilcoxon signed-rank test and effect sizes).

| Measure   | Intervention condition | Baseline M (SD) | Post-condition M (SD) | Z     | p   | r   | Intervention condition | Baseline M (SD) | One-month follow-up M (SD) | Z     | p   | r   |
|-----------|-----------------------|----------------|----------------------|-------|-----|-----|-----------------------|----------------|---------------------------|-------|-----|-----|
| PCL-5     | Control condition     | 12.39 (9.47)   | 8.89 (9.22)          | -4.39 | <.00 | -.35| Intervention condition | 10.73 (8.17)   | 6.08 (8.48)               | -5.68 | <.00 | -.45|
|           | n = 84                | n = 85         |                      |       |     |     | Control condition     | n = 79         | n = 79                    |       |     |     |
| PTCI      | Control condition     | 67.14 (30.02)  | 60.20 (29.09)        | -3.13 | <.00 | -.24| Intervention condition | 61.13 (23.00)  | 49.99 (22.78)             | -5.22 | <.00 | -.42|
|           | n = 83                | n = 83         |                      |       |     |     | Control condition     | n = 78         | n = 78                    |       |     |     |
| RES       | Control condition     | 24.42 (4.91)   | 25.64 (4.79)         | -2.84 | <.00 | -.22| Intervention condition | 24.87 (4.67)   | 26.54 (4.82)              | -4.19 | <.00 | -.33|
|           | n = 85                | n = 85         |                      |       |     |     | Control condition     | n = 79         | n = 79                    |       |     |     |
| SSL-6     | Control condition     | 8.76 (2.93)    | 8.26 (2.82)          | -2.04 | <.00 | -.16| Intervention condition | 8.38 (2.68)    | 8.16 (2.88)               | -2.74 | <.00 | -.22|
|           | n = 82                | n = 82         |                      |       |     |     | Control condition     | n = 76         | n = 76                    |       |     |     |

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tools. Also, the U.S. veterans were in active PTSD treatment, and received (face-to-face) guidance on how to use the app, which could positively influence the results (Cernvall et al., 2018; Possemato et al., 2016). Since all the perceived helpfulness and satisfaction items are specifically aimed at PTSS, future research (especially in populations with lower levels of PTSS) should include items on other trauma-related outcomes and factors, such as negative trauma-related cognitions, psychological resilience, overall stress level, and psychosocial functioning (Kuhn et al., 2017). To potentially improve the usability and user satisfaction of the app as a standalone tool, the overall purpose of the app, as well as rationales for specific app exercises, and guidance throughout the app submenus via for instance an online tutorial should be provided (Cernvall et al., 2018). Also, as previously suggested, mental health interventions delivered online or via apps in general could be made more appealing and engaging by incorporating interactive elements, pictures, and video and audio features (Berry, Lobban, Emsley, & Bucci, 2016).

The current study has several important strengths. Our study concerns an at risk population with limited PTSS, who generally receive little attention, and for whom evidence-based self-help is scarce (Marshall et al., 2001; Robertson & Perry, 2010). The study is an RCT with a control condition, large sample size, follow-up assessment, and valid questionnaires. Besides the efficacy of the app, the usability and user satisfaction were examined. To control for discrepancies between self-reported and objective data on app usage, objective individual usage patterns were gathered via a back-office system. The following limitations must be mentioned apart from the previously discussed attrition. The results of our study are generalizable to Dutch, mainly well-educated HCPs, but generalization to other high-risk professions and the general population with various cultural backgrounds and education levels remains to be confirmed. A continuous measure on active app usage in minutes is missing and therefore the relationship between app usage (in minutes) and outcome measures is lacking. Also, the long-term effects of the app beyond-one month are unknown.

In conclusion, since trauma and PTSS are common (Kessler et al., 2017) and considered a public health issue (Magruder, McLaughlin, & Elmore Borbon, 2017), there is an urgent need to explore how to deliver easy-accessible evidence-based interventions to individuals affected by trauma. Self-help apps could be useful to assess trauma-related symptoms and resilience (van der Meer, Bakker, Schrieken, Hoofwijk, & Olff, 2017), to monitor mental health symptoms during the acute post-trauma period, to reduce these symptoms, and possibly prevent them (Kuhn et al., 2018; Olff, 2015). Our study suggests that SUPPORT Coach may potentially provide easy-accessible low-intensity self-help to empower individuals following trauma and reduce (subclinical) negative trauma-related consequences. Further research is needed to replicate our findings.

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