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## A video-based smartphone app (“VIDEA bewegt”) for physical activity support in German adults, a single armed observational study

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1 **A video-based smartphone app (“VIDEA bewegt”) for physical activity support in**  
2 **German adults, a single armed observational study**

3  
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17  
18 **ABSTRACT**

19 **Objectives**

20 The primary objective of this study was to investigate the effect of the video-based smartphone  
21 app (‘VIDEA bewegt’) over eight program weeks on physical activity in German adults.

22 **Design**

23 The study used a single-arm observational design, assessing the app’s effectiveness under  
24 real-life conditions. Data was collected from July 2019 to July 2020.

25 **Setting**

26 The app is enabling users to access video-based educational content via their smartphone. A  
27 clinical visit or in-person contact was not required.

28 **Participants**

29 All individuals registered in the app were invited to take part in the study.

30 **Interventions**

31 The app aims to increase physical activity in everyday life. It combines educative videos on  
32 life-style related benefits and instructional videos of strength and endurance exercises to do  
33 at home with motivational components like goal setting, documentation of progress, and  
34 personalized messages.

35 **Primary and Secondary outcome measures**

36 Primary outcomes were physical activity based one MET minutes per week (metabolic  
37 equivalent) and step numbers.

1 38 Secondary outcomes included physical self-efficacy (motivational, maintenance, recovery  
2 self-efficacy), health-related quality of life: MCS (mental health component summary score)  
3 and PCS (physical health component summary score).  
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## 6 41 **Results**

7 42 Of 97 people included in the data analysis, 55 successfully completed the program and all  
8 questionnaires. Significant increases over eight program weeks (between T0 and T2) were  
9 observed in physical activity based on MET-Minutes per week, health-related quality of life,  
10 and recovery self-efficacy. Time spent sitting and BMI significantly decreased for those  
11 completing the program.  
12  
13

## 14 46 **Conclusions**

15 47  
16 48 Although significant benefits of physical activity were observed following a complete-case-  
17 analysis, results should be dealt with caution. Studies with a larger and less heterogeneous  
18 sample and robust study designs able to measure causal effects would be desirable.  
19  
20

## 21 50 **Trial registration**

22 51  
23 52 German Clinical Trials Register (DRKS): Evaluation of an app-based activity intervention for  
24 statutory health insured people. DRKS-ID: DRKS00017392. (14 June 2019)  
25  
26

## 27 54 **Strengths and limitations of this study**

- 28 55  
29 56
- 30 57 • The evaluation of the intervention is carried out under real-life conditions.
  - 31 58 • Various approaches were used to describe the effects of the intervention.
  - 32 59 • The small sample size, broad inclusion criteria for participation bias and a high dropout  
33 rate limit the internal validity.
  - 34 60 • Due to its observational design and the absence of a control group and randomisation,  
35 this study can only provide limited data on how individual app components contributed  
36 to the overall effect of the app.
  - 37 61 • Most data collected was based on self-assessment.  
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## 44 65 **INTRODUCTION**

### 45 66 **Background**

46 67 Non-communicable diseases are substantially caused by lifestyle-associated factors like  
47 insufficient physical activity [1]. In addition to non-communicable diseases, activity also  
48 influences quality of life and mental health [2]. To prevent chronic diseases like diabetes, it is  
49 recommended to promote physical activity across all age groups [3–6]. Effective strategies to  
50 increase motivation and reduce barriers for behaviour change require sustained efforts and  
51 ongoing support [7–9]. Behavioral change support by the use of smartphones in particular  
52 seems promising due to their widespread use and low barriers to participation uptake [10,11].  
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1 74 Smartphone app based interventions providing performance-related feedback, psychosocial  
2 75 networking and goal setting have been found to effectively increase physical activity [12–16].  
3 76 Additionally, self-efficacy has been widely demonstrated to positively impact a range of health-  
4 77 promoting behavioral processes [17–19]. According to the Health Action Process Approach  
5 78 (HAPA), different subcomponents of self-efficacy can be distinguished [20]. Particularly  
6 79 decisive is the stability respectively variability of the subcomponents in the present study.  
7 80 Digital interventions have the unique potential to combine these effective strategies while  
8 81 keeping user acceptance high [21,22].  
9 82

10 83 Despite these known components of successful behavior change, the generation of evidence  
11 84 in the field of digitally supported behavior change predominantly focused on apps developed  
12 85 in relation to scientific studies, rather than evaluating freely accessible apps [23,24]. As a  
13 86 result, despite the increasing number of health apps on the market, the minority of them is  
14 87 based on strong empirical and scientific evidence [10,25–28]. Scientific evaluations of  
15 88 available apps offer great potential for improving both present and future apps [29–31]. While  
16 89 studies show promising results on the effectiveness of these interventions to prevent [32] or  
17 90 successfully manage [6,33] chronic lifestyle-related diseases, e.g. by using videos for  
18 91 preventive purposes,[34] the strategies needed to achieve sustainable behavior change seem  
19 92 to have received little attention [12].

20 93 Reasons for the described limited evidence base of digital health apps include methodological  
21 94 challenges during evaluation. In order to guide evidence-based decision making, RCTs are  
22 95 regarded as highest level [35]. However, digital health interventions usually comprise multiple  
23 96 components and are mostly designed as modular interventions offering tailored as well as  
24 97 performance-based adaptations or feedback [36]. This may end up in circumstances where  
25 98 RCTs may not be feasible. As such, challenges including randomization, timing of  
26 99 assessment, acceptance by patients and physicians, blinding, as well as defining control  
27 100 groups and relevant endpoints need to be considered [37]. In addition to the described  
28 101 challenges during evaluation, limited guidance is available on the mid- to long term outcomes  
29 102 [38,39].

30 103 Therefore, the primary objective of this study was to investigate the effect of the video-based  
31 104 smartphone app ('VIDEA bewegt') over eight program weeks on physical activity (MET-  
32 105 minutes per Week and steps per day) in German adults. Secondary objectives were to analyse  
33 106 the associated changes in self-efficacy and health-related quality of life.  
34 107

## 35 108 **Hypotheses**

36 109 The users of 'VIDEA bewegt' who participate in the study increase their average daily step  
37 110 count and achieve a higher number of metabolic equivalent (MET) minutes per week, a  
38 111 significantly higher health-related quality of life, a significantly higher motivational,

1 112 maintenance and recovery self-efficacy after the first four weeks, and after completion of the  
2 113 eight-week course, compared to the beginning of data collection.  
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## 5 114 6 115 7 116 **MATERIALS AND METHODS** 8 9

10 117  
11 118 A detailed study protocol following important recommendations formulated by Eysenbach and  
12 119 the CONSORT-EHEALTH Group [40] was published prior to the data analysis [41].  
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### 16 121 **Study design and summary of intervention**

17 122 Data collection took place from July 2019 to July 2020. The evaluation of the app 'VIDEA  
18 123 bewegt' is designed as a single-arm observational study, assessing the app's effectiveness  
19 124 and usability under real-life conditions. The smartphone app 'VIDEA bewegt' is a video-based  
20 125 program to increase physical activity in everyday life. The app is divided into eight program  
21 126 weeks, each of which follows a consistent structure. The core of the app are four videos per  
22 127 program week. Theoretical videos explain and illustrate the importance of exercise and  
23 128 lifestyle, as well as ways to build up motivation. Practical videos present exercises to improve  
24 129 strength and endurance in a way which can be followed without the use of supplies.  
25 130 Additionally, motivational components such as goal setting, progress documentation, and  
26 131 personal messages are included. More extensive information can be found in the study  
27 132 protocol [41].  
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### 39 134 **Setting**

40 135 'VIDEA bewegt' is an app enabling users to access educational content via their smartphone  
41 136 anywhere and at any time. It was made available on the German market for Android and iOS  
42 137 in March 2019. Costs of the program are partially reimbursed by health insurance companies.  
43 138 Further information can be found on the German website [42].

44 139 A clinical visit or in-person contact with a physician or diabetes specialist was not required.  
45 140 However, it was possible to consult experts in preventative health care and sports science via  
46 141 an integrated chat function. Problems could also be discussed with other users and experts in  
47 142 a forum.  
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### 51 143 52 144 **Participants**

53 145 To register in the app, interested individuals had to be of legal age ( $\geq 18$  years old) and declare  
54 146 that they were free of serious medical conditions such as heart failure. All registered  
55 147 individuals were invited to the study without further restriction.  
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## 149 **Patient and public involvement**

150 Potential participants were included in pretesting the questionnaires in order to assess their  
151 logic, understandability, and technical performance. A usability test with ten individuals  
152 provided insight in strengths and weaknesses of the app. Additionally, all study participants  
153 were asked to answer questions regarding their experience with the app's components. All  
154 data that made it possible to further optimize the app was forwarded to the developing  
155 company.

## 157 **Procedure**

158 App users interested in the study received an email and access to the first online  
159 questionnaire, which included the consent form and privacy policy. Individuals who completed  
160 the first questionnaire became study participants and received further questionnaires after  
161 completion of the fourth and eighth program weeks. In addition, internal app usage data  
162 including step counts were collected. For the analysis, three relevant time points were defined  
163 at which the individual outcome variables would be compared. The program start defined the  
164 time point T0, the program half the time point T1 and the program completion the time point  
165 T2. Participants received an email with a link to the online questionnaire at each time point.  
166 As such, data collection depended on participants' program usage. If a questionnaire was not  
167 completed after two days, the participants received a reminder. The study was conducted  
168 entirely digitally.

## 170 **Outcomes**

171 *Primary outcomes* were physical activity based one MET minutes per week (metabolic  
172 equivalent) and step numbers.

173 *Secondary outcomes* included physical self-efficacy (motivational, maintenance, recovery  
174 self-efficacy), health-related quality of life: MCS (mental health component summary score)  
175 and PCS (physical health component summary score).

176 To measure the outcome variables, validated measurement instruments were applied. The  
177 Global Physical Activity Questionnaire (GPAQ) was used to record MET minutes per week  
178 [43,44]. The assessment of health-related quality of life is based on the SF-8 questionnaire  
179 [45,46]. Self-efficacy was measured in the three dimensions of motivation self-efficacy,  
180 maintenance self-efficacy and recovery self-efficacy [47,48]. Step counts per day were entered  
181 into the app by the users themselves. For the comparison between T0 and T2, all persons  
182 were included who had entered their steps on at least 5 of 14 days at both start and end of  
183 the program. For the comparison between T0 and T1, all persons who had entered their steps  
184 on at least 3 of 7 days were included.

## 186 **Statistical analyses**



187 Sociodemographic data and user behaviour were analysed descriptively. The Shapiro-Wilk-  
 188 Test was used to test for normal distribution. The hypotheses were tested using a one-sided  
 189 Wilcoxon-Test for dependent samples at T0, T1 and T2 due to lack of normal distribution (see  
 190 Table 3 – Statistical methods). A subgroup analysis was not conducted on account of the small  
 191 sample size. Due to the exploratory nature of the data analysis, Bonferroni correction was  
 192 omitted [49,50]. Instead, an exploratory analysis was added to separate individuals who  
 193 completed the program and who showed an increase in activity.  
 194 Average values were calculated for the number of steps per day. For the comparison of T0  
 195 and T2, all persons were included who synchronized steps on at least 5 of 14 days at the  
 196 beginning and end. For the comparison of T0 and T1, persons with at least three out of seven  
 197 days of synchronization were included following the same method.  
 198 The analysis was conducted as a complete case analysis.

## 200 RESULTS

### 202 Description of the sample

203 During the data collection period, 1519 individuals registered with the app. Of those, 103  
 204 individuals (6,8%) followed the study invitation and completed the first questionnaire. Two  
 205 people withdrew their participation during the survey, and four people were excluded from the  
 206 analysis because of not completing the first questionnaire at the beginning of program use.  
 207 Consequently, 97 people were included in the data analysis, 55 of whom successfully  
 208 completed the program and all questionnaires (see Table 1).

210 *Table 1 Characteristics of the study population*

Overall n	97
Age mean (SD) in years	47.52 (13.52)
Sex	80 female (82%), 17 male (18%)
Body-Mass-Index median (IQR) in kg/m <sup>2</sup>	26.26 (8.8)
Marital status	
Married	57
Living in stable relationship	15
Divorced, separated	10
Single	11
Widowed	3
Other	1
Level of education	
completed training	32

completed studies	35
high school	14
secondary school	13
other	4
Gainful employment	
full-time	49
half-time	16
retired	16
part-time employed	7
not employed	9
Other Sports courses <sup>1</sup>	
Yes	49
No	48
Other Health apps <sup>2</sup>	
Yes	30
No	67

Notes. 1 = Participation in sports courses, 2 = Use of other health apps in addition to the VIDEA program. SD=standard deviation, IQR=Interquartile range

The median duration of program use was 68 days (Interquartile range (IQR) 64 days). The female participants accounted for 82% of the participants.

### Comparison of persons with and without program completion

A total of 42 out of 97 study participants had not completed the program, which resulted in 42 (43%) incomplete datasets. Due to the proportion of missing data exceeding 40%, imputation methods were not used [51].

Comparing the groups of persons with and without program completion, age, gender distribution and marital status did not differ substantially. In the group with program completion, the proportion of persons with a university degree was larger. The proportion of full-time employees was smaller resulting in a larger proportion of retired persons. In the group with program completion, the proportion of people who used additional health apps was smaller. BMI was also lower here, while health-related quality of life and physical activity did not differ.

### Physical Activity

The hypothesis that physical activity increases significantly between program start and completion can be supported for MET minutes per week. In contrast, the hypothesis that there is a significant increase in MET minutes already within the first half of the program cannot be

232 confirmed (see Table 2). For the number of steps per day, neither a significant increase in the  
 233 first half nor over the entire program time was detected.

234  
 235 Table 2 Primary outcome measures, using asymptomatic one-sided Wilcoxon-tests

	Median (IQR) n=55	T0 vs. T1	T1 vs. T2	T0 vs. T2
MET minutes per week	T0: 2400 (3140)	$z=-1.391$ , $p=0.082$ , $n=55$ , $r=0.188$	$z=-1.778$ , $p=0.038$ , $n=55$ , $r=0.240$	$z=-1.927$ , $p=0.027$ , $n=55$ , $r=0.260$
	T1: 2760 (4100)			
	T2: 2640 (5680)			
Steps per day	T0: 7043 (4283), n=61	$z=-0.470$ , $p=0.638$ , $n=31$ , $r=0.084$		$z=-1.562$ , $p=0.061$ , $n=27$ , $r=0.301$
	T1: 6820 (6590), n=39			

236 IQR=Interquartile range, MET=metabolic equivalent, T0=program start, T1=program half, T2=program completion

237

### 238 Health related quality of life and Self-efficacy

239 The hypotheses that health-related quality of life based on the Physical Component Summary  
 240 (PCS) and the Mental Component Summary (MCS) increases significantly in the first half of  
 241 the program and over the entire program period can both be confirmed. Looking at self-  
 242 efficacy, the formulated hypotheses can only be confirmed for recovery self-efficacy, where  
 243 there was a significant increase over the entire program period. In contrast, there were no  
 244 significant increases in motivational and maintenance self-efficacy (see Table 3).

245 Table 3 Primary outcome measures, using asymptomatic one-sided Wilcoxon-tests

	Median (IQR) n=55	T0 vs. T1	T1 vs. T2	T0 vs. T2
PCS	T0: 49.74 (13.06)	$z=-2.409$ , $p=0.008$ , $n=55$ , $r=0.325$	$z=-1.694$ , $p=0.045$ , $n=55$ , $r=0.228$	$z=-3.050$ , $p=0.001$ , $n=55$ , $r=0.411$
	T1: 51.80 (13.34)			
	T2: 50.14 (9.33)			
MCS	T0: 47.80 (12.17)	$z=-3.599$ , $p<0.001$ $n=55$ , $r=0.485$	$z=-0.537$ , $p=0.296$ , $n=55$ , $r=0.072$	$z=-3.484$ , $p<0.001$ , $n=55$ , $r=0.470$
	T1: 52.49 (8.09)			
	T2: 52.31 (9.56)			
motivational self-efficacy	T0: 3.67 (1.00)	$z=-0.528$ , $p=0.238$ , $n=55$ , $r=0.071$	$z=-0.421$ , $p=0.737$ , $n=55$ , $r=0.057$	$z=-0.125$ , $p=0.574$ , $n=55$ , $r=0.017$
	T1: 3.67 (1.16)			
	T2: 3.67 (1.66)			
maintenance self-efficacy	T0: 3.00 (1.00)	$z=-1.043$ , $p=0.142$ , $n=55$ , $r=0.141$	$z=-0.592$ , $p=0.289$ , $n=55$ , $r=0.08$	$z=-1.199$ , $p=0.092$ , $n=55$ , $r=0.162$
	T1: 3.00 (1.00)			
	T2: 3.33 (1.33)			
recovery self-	T0: 3.00 (0.84)	$z=-0.368$ ,	$z=-2.075$ ,	$z=-1.850$ ,

efficacy	T1: 3.67 (1.00)	$p=0.323$ , $n=55$ ,	$p=0.019$ , $n=55$ ,	$p=0.032$ , $n=55$ ,
	T2: 4.00 (2.00)	$r=0.05$	$r=0.28$	$r=0.249$

IQR=Interquartile range, PCS=Physical Component Summary Score, MCS=Mental Component Summary Score, T0=program start (baseline), T1=program half, T2=program completion

### Additional Analysis

In addition, to the main hypotheses described above, further calculations were performed using the data from the GPAQ and the general questionnaire.

In a first analysis, using only program completers with complete data sets ( $n=55$ ), the Body Mass Index (BMI) was analyzed, which decreased significantly over the entire program period and between T1 and T2. Furthermore, the time participants spend sitting per day decreased significantly between T0 and T2 as well as T1 and T2. In addition to calculating MET minutes per week, the GPAQ also allows for an analysis of separate activity dimensions (work, transportation, and leisure). The analysis showed that activity during leisure time increased significantly, while activity at work and in transportation did not change significantly (see Table 4).

Because a large proportion of participants already reported high values of MET-minutes per week ( $>4000$  MET-minutes per week) at T0 and were thus less likely to benefit from further increases in activity [52], the comparison between T0 and T2 was repeated for all individuals with baseline activity of less than 4000 MET-minutes per week. Results indicate a significant increase in activity for these participants with large effect sizes (see Table 4).

Table 4 – Additional analyses using asymptomatic two-sided Wilcoxon-tests

	Median (IQR)	T0 vs. T1	T1 vs. T2	T0 vs. T2
BMI in $\text{kg}/\text{m}^2$ , $n=55$	T0: 25.51 (8.45)	$z=-0.010$ ,	$z=-3.117$ ,	$z=-2.445$ ,
	T1: 25.95 (8.54)	$p=0.992$ ,	$p=0.002$ ,	$p=0.014$ , $r=0.330$
	T2: 24.91 (7.26)	$r=0.001$	$r=0.420$	
Time spent sitting in hours, $n=55$	T0: 6 (4)	$z=-0.420$ ,	$z=-2.962$ ,	$z=-2.472$
	T1: 6 (4)	$p=0.675$ ,	$p=0.003$ ,	$p=0.013$ , $r=0.333$
	T2: 5 (4)	$r=0.091$	$r=0.399$	
Active minutes in leisure time in minutes per day, $n=55$	T0: 25.71 (22.86)	$z=-3.053$ ,	$z=-1.171$ ,	$z=-2.898$ ,
	T1: 27.31 (30.00)	$p=0.002$ ,	$p=0.242$ ,	$p=0.004$ , $r=0.391$
	T2: 31.43 (51.43)	$r=0.412$	$r=0.158$	
Active minutes at work, in minutes per day, $n=55$	T0: 12.86 (64.29)	$z=-0.314$ ,	$z=-0.403$ ,	$z=-1.559$ ,
	T1: 21.43 (85.71)	$p=0.753$ ,	$p=0.687$ ,	$p=0.119$ , $r=0.210$
	T2: 14.29 (100.00)	$r=0.042$	$r=0.054$	

Active minutes in transport, in minutes per day, n=55	T0: 21.43 (40.00)	$z=-0.669,$	$z=-1.789,$	$z=-0.510$
	T1: 21.43 (24.29)	$p=0.503,$	$p=0.074,$	$p=0.610, r=0.069$
	T2: 17.14 (31.43)	$r=0.090$	$r=0.241$	
MET-minutes per day of people with initial activity <4000 MET- Minutes per day, n=41	T0: 1640 (1780)	$z=-3.882,$	$z=-1.109,$	$z=-3.039,$
	T1: 2560 (2756)	$p<0.001,$	$p=0.267,$	$p=0.002, r=0.475$
	T2: 2160 (2510)	$r=0.606$	$r=0.173$	

266 IQR=Interquartile range, BMI=Body Mass Index, MET= metabolic equivalent, T0=program start, T1=program half, T2=program  
267 completion

268

## 269 DISCUSSION

270 The primary aim of this study was to assess the effects of the video-based smartphone app  
271 'VIDEA bewegt' on physical activity and related outcomes in German adults under real-life  
272 conditions. Individuals who completed the program experienced a significant increase in  
273 physical activity based on several parameters and health-related quality of life. Furthermore,  
274 the recovery self-efficacy increased significantly as well.

275 Data was collected from 97 study participants to provide the basis for the conducted study.  
276 Women accounted for more than three-quarters of the sample. It is known that women tend  
277 to be more interested in health interventions than men and are easier to convince of new  
278 interventions [53,54]. Additionally, well-educated people often have a greater interest in health  
279 interventions. It is therefore not surprising that the study mainly involved people who had  
280 completed their education and were in full-time employment [54].

281

282 *Effectiveness:* The 55 subjects with program completion reported a median physical activity  
283 of 2400 MET minutes per week at T0. For people in Germany, a representative study  
284 determined an average value of 630 MET minutes per week [55]. Consequently, the sample  
285 was physically active to an above-average degree. Insufficient physical activity is defined by  
286 the WHO as less than 600 MET minutes per week [56]. However, it is known that physical  
287 activity should be much higher in order to effectively reduce risks of chronic diseases [52].  
288 Despite the relatively high baseline physical activity levels of the sample, participants  
289 completing the program showed improvements of physical activity measured by MET-Minutes  
290 per week (significant increase T0/T2 and T1/T2 with  $r=0.260$  and  $r=0.188$ ). Including only  
291 those individuals with less than 4000 MET minutes per week at baseline, this increase was  
292 significant with medium and strong effect sizes ( $r=0.475$  and  $r=0.606$ ). For this part of the

1 293 sample, MET minutes per week increased by 32%. Similar rates of activity increase were also  
2 294 found in other studies [10,15].  
3  
4 295 Step counts per day are a widely used measure of physical activity [57]. However, only few  
5 296 and incomplete data sets were available in the present study, which is why results have to be  
6 297 dealt with caution. The step count data sets did not show any significant increases in the  
7 298 number of steps per day. It would have been desirable to compare the objective step counts  
8 299 with the less objective MET minutes, as recommended [58]. However, since only 27 of 55  
9 300 people synchronized their steps at the beginning and end of the program on at least five of 14  
10 301 days, no such comparison was made.  
11  
12 302 Sedentary time per day decreased significantly from a median of six to five hours. In fact, five  
13 303 hours of sedentary time were found to be the average of the German population [59]. While  
14 304 total mortality is significantly reduced by replacing one hour of sedentary time with activity [60],  
15 305 the decrease in sedentary time observed in the study can be interpreted as clinically relevant.  
16 306 The median BMI of the 97 study participants of 26.26 kg/m<sup>2</sup> at baseline is comparable to similar  
17 307 studies [10,15,61]. It significantly decreased with medium effect size ( $r=0.330$ ) between T0  
18 308 and T2 for the 55 individuals with program completion. As such, while the median BMI lied in  
19 309 the range of overweight ( $>25\text{kg/m}^2$  [62]) at baseline, participants completing the program  
20 310 improved to ranges of normal weight ( $<25\text{kg/m}^2$ ) after eight program weeks with individually  
21 311 different time periods being needed (median program use of 68 days). Considering weight  
22 312 changes as the basis of BMI values, clinically relevant weight decreases of at least 5% were  
23 313 found in 7 of 55 subjects [63].  
24  
25 314 Health-related quality of life increased significantly in the first half of the program, but also over  
26 315 the entire program period, with a medium effect size. In 2004, norm values of PCS=50.30 and  
27 316 MCS=53.25 were determined for the German population [64]. In the PCS, the number of  
28 317 people above the norm did not change and remained at 27/55. In the MCS, only 12/55 people  
29 318 were above the norm at the beginning of the program and 25/55 at the end of the program.  
30 319 Overall, however, the health-related quality of life could not be rated as above average, since  
31 320 the medians were below the norm at all time points. A clinically relevant change in PCS or  
32 321 MCS of at least three points [65] was found in the PCS for 27/55 subjects and in the MCS for  
33 322 37/55 subjects.  
34  
35 323 While motivational and maintenance self-efficacy did not change during the intervention, there  
36 324 was a significant increase in recovery self-efficacy for individuals completing the program  
37 325 (recovery self-efficacy  $r=0.249$ ). Luszczynska et al. demonstrated that recovery self-efficacy  
38 326 has a stronger predictive influence on physical activity than maintenance self-efficacy [66].  
39 327 Based on the health action process approach (HAPA), these findings seem conclusive, as  
40 328 recovery self-efficacy is particularly important for the implementation and execution of new  
41 329 behavior [67]. The increase of recovery self-efficacy emerged between T1 and T2, while the  
42 330 comparison between T0 and T1 did not show an increase. It is known that recovery self-

1 331 efficacy is especially important in later stages of behavior change when barriers and failures  
2 332 occur, with overcoming such setbacks being the main challenge. High recovery self-efficacy  
3 333 also is important for resuming health-promoting behaviors after an interruption [66]. In this  
4 334 present study, the rather informal character as well as participants' freedom to execute the  
5 335 whole program resulted in heterogeneous intervention durations. Thus, individuals who  
6 336 successfully completed the intervention may have been particularly effective at coping with  
7 337 such interruptions. It is possible that the positive learning experiences contributed to an  
8 338 improvement in recovery self-efficacy, as well.

14 339 For digital interventions, the correlation of high self-efficacy with high exercise frequency and  
15 340 an increase in health-related parameters is well known [68]. For example, it has already been  
16 341 described that self-efficacy increased during an intervention to reduce BMI [69]. The results of  
17 342 the present study confirm the important role of self-efficacy in digital interventions. Accordingly,  
18 343 the specific relevance of each dimension of self-efficacy as well as the maintenance of  
19 344 behavior changes reflected by mid-to-long-term follow-ups should be addressed in future  
20 345 studies. Research on self-efficacy may help to develop more effective and better  
21 346 individualizable interventions.

26 347

28 348 *Dropouts:* The fraction of people responding to a study invitation is often less than ten percent  
29 349 [70]. In the present study, 6.8 percent of the app users became study participants. Of the 97  
30 350 people included in the analysis, only 55 completed the program. It is known that loss of  
31 351 interest, hidden costs, or complicated use can be responsible for dropout [71]. The sample  
32 352 covered an age range of 22-75 years and had a mean age of 48 years. Similar age averages  
33 353 can also be found in other studies [10,15,61]. An analysis of individual subgroups would have  
34 354 been desirable, but would have required a larger sample [72].

39 355

## 41 356 **Limitations**

42 357 An important strength of this study is that it was conducted under real-life conditions.  
43 358 Furthermore, objective and subjective approaches of measurements were combined. Another  
44 359 strength is the user-centered study design, in which potential users were involved in the design  
45 360 of the questionnaires and the app [73].

48 361 However, the following limitations of our approach should be taken into account. The number  
49 362 of app users remained below expectations, resulting in a small sample that did not allow for  
50 363 subgroup analysis. Though the sample size can be regarded as small, it is comparable to  
51 364 other projects [12].

55 365 Voluntary study participation may have resulted in a selection bias, with primarily participation  
56 366 of highly motivated individuals [74]. Of these individuals, only those with program completion  
57 367 were analyzed in the complete case analysis, which entails a potential overestimation of  
58 368 positive effects [75]. Compared to those who did not complete the program, these individuals

1 369 used other health apps less frequently and had a lower BMI. Therefore, it is likely, that  
2 370 especially individuals who previously had little app experience completed the program.  
3 371 Furthermore, a financial incentive was offered for study participation through reimbursement  
4 372 of program costs, which may also have influenced the sample composition [70].

5 373 Broad inclusion criteria with only limited restrictions caused an inhomogeneous study  
6 374 population, in terms of individual characteristics such as age, BMI and baseline activity. This  
7 375 is matched by the fact that many results show wide interquartile ranges and can be considered  
8 376 as inconsistent. Due to its observational design, the absence of a control group and missing  
9 377 randomisation, this study can only provide limited data on how individual app components  
10 378 contributed to the overall effect of the app. This is relevant as the investigated app can be  
11 379 defined as a complex intervention entailing multiple components. In addition, the observational  
12 380 study design did not allow for controlling potential confounders relating to the use of additional  
13 381 apps in parallel to study participation. Thus, the small sample size made it difficult to account  
14 382 for confounding factors during data analysis. Additionally, it was not possible to conclusively  
15 383 clarify which individuals could benefit most from app use.

16 384 The app was regularly updated by the responsible company during the period of data  
17 385 collection, without changing any essential content. Nevertheless, small changes of the design,  
18 386 or the app performance could have led to different display of the content.

19 387 Most of the data collected is based on self-assessment during an app use in real life.  
20 388 Additionally, the time of completing questionnaires was based on the program duration which  
21 389 substantially differed between participants. This is in line with the approach of a pragmatic  
22 390 study but may have introduced a risk of measurement bias affecting internal validity

23 391

## 24 392 **Outlook**

25 393 While most apps for increasing physical activity focus on documenting activity,[12,76] “VIDEA  
26 394 bewegt” offers a novel concept in which video-based information, practical guidance and  
27 395 helpful tips are provided. Such interventions are particularly in demand at times of the Corona  
28 396 pandemic to counteract restricted activity through lockdown policies,[77] minimizing the risk of  
29 397 severe Corona disease [78]. The results of the one-year follow-up are still awaited, which will  
30 398 clarify the important question of the sustainability of observed effects. With special regard to  
31 399 the described limitations of this study, future projects should aim for a larger sample to allow  
32 400 for subgroup analyses. At the same time, the proportion of missing data should be minimized  
33 401 by including a less heterogeneous sample. In addition, a more direct way to contact the  
34 402 participants should be considered. The quality of the results would also benefit from data  
35 403 collection methods not solely based on self-reported values.

36 404

## 37 405 **Conclusion**

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1 406 Although significant benefits of physical activity were observed following a complete-case-  
2 407 analysis after eight program weeks, results should be dealt with caution. Using "VIDEA  
3 408 bewegt" resulted in an increase of physical activity for some participants. As such, significant  
4 409 increases in MET minutes per week and health-related quality of life as well as significant  
5 410 decreases in time spent sitting and BMI were observed for program completers. Overall, the  
6 411 combination of educative strategies, video-based exercise tutorials and motivational support  
7 412 seemed promising. Future research is warranted to evaluate the effectiveness of the whole  
8 413 program using rigorously conducted trials while enrolling a larger number of participants.  
9 414

## 15 415 **ETHICS AND DISSEMINATION**

### 19 417 **Ethics approval**

21 418 After an ethics application was submitted to the Ethics Committee of the Technical University  
22 419 of Dresden on 12 April, the Ethics Committee approved the study on 25 May 2019 (EK  
23 420 272062019).

### 25 421 **Consent to participate**

27 422 The informed consent to participate is obtained written by clicking a button in the first online  
28 423 questionnaire in accordance with the DSGVO as a prerequisite for participation  
29 424

## 32 425 **STATEMENTS**

### 36 427 **Authors' contributions**

38 428 TF and PS wrote the manuscript, collected the data, and performed the data analysis. TF  
39 429 focused on the analysis on physical activity, health-related quality of life, and the exploratory  
40 430 analysis, while PS focused on self-efficacy. PEHS advised and provided feedback and  
41 431 reviewed the manuscript. PT regularly provided feedback on the overall study flow and  
42 432 participated in the writing of the manuscript. All authors reviewed and approved the final  
43 433 version of the manuscript before submission.  
44 434

### 49 435 **Competing interests**

51 436 The principal investigator Prof Schwarz was involved in the development and implementation  
52 437 of the app 'VIDEA bewegt' as a medical expert.

54 438 He is responsible for the medical and theoretical background and is shown in the app's videos.  
55 439 He received no payment for his participation in the app.  
56 440

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8 446

### 9 447 **Data availability**

10 448 Data are available upon reasonable request.

11 449 Individual participant data collected during the trial will be available after  
12 450 deidentification and completion of data collection.

13 451 Data will be shared with researchers who provide a methodologically sound  
14 452 proposal. Proposals should be directed to peter.schwarz@uniklinikum-dresden.de.

15 453 To gain access, data requestors will need to sign a data access agreement.  
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## STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1-2
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2-3
Objectives	3	State specific objectives, including any prespecified hypotheses	3
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	4
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5
Bias	9	Describe any efforts to address potential sources of bias	5
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5-6
		(b) Describe any methods used to examine subgroups and interactions	
		(c) Explain how missing data were addressed	
	6	(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	7

Continued on next page

<b>Results</b>			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6
		(b) Give reasons for non-participation at each stage	6
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6-7
		(b) Indicate number of participants with missing data for each variable of interest	7
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	7
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7-8
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	10
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12-13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13-14
Generalisability	21	Discuss the generalisability (external validity) of the study results	14
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	14-
			15

\*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).

# BMJ Open

## A video-based smartphone app ("VIDEA bewegt") for physical activity support in German adults, a single armed observational study

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1 **A video-based smartphone app (“VIDEA bewegt”) for physical activity support in**  
2 **German adults, a single armed observational study**

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6 Tillmann Fischer<sup>1\*</sup>, Paul Stumpf<sup>1\*</sup>, Peter E.H. Schwarz<sup>1,2,3</sup>, Patrick Timpel<sup>1</sup>  
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## 27 **ABSTRACT**

### 28 **Objectives**

29 The primary objective of this study was to investigate the effect of the video-based smartphone  
30 app (‘VIDEA bewegt’) over eight program weeks on physical activity in German adults.  
31

### 32 **Design**

33 The study used a single-arm observational design, assessing the app’s effectiveness under  
34 real-life conditions. Data were collected from July 2019 to July 2020.  
35

### 36 **Setting**

37 The app is enabling users to access video-based educational content via their smartphone. A  
38 clinical visit or in-person contact was not required.  
39

### 40 **Participants**

41 All individuals registered in the freely available app were invited to take part in the study.  
42

### 43 **Interventions**

44 The app aims to increase physical activity in everyday life. It combines educative videos on  
45 life-style related benefits and instructional videos of strength and endurance exercises to do  
46 at home with motivational components like goal setting, documentation of progress, and  
47 personalized messages.  
48

### 49 **Primary and Secondary outcome measures**

50 Primary outcomes were physical activity based one MET minutes per week (metabolic  
51 equivalent) and step numbers.  
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37 Secondary outcomes included physical self-efficacy (motivational, maintenance, recovery  
38 self-efficacy), health-related quality of life: MCS (mental health component summary score)  
39 and PCS (physical health component summary score).

## 40 **Results**

41 Of 97 people included in the data analysis, 55 successfully completed the program and all  
42 questionnaires. Significant increases over eight program weeks (between T0 and T2) were  
43 observed in physical activity based on MET-Minutes per week, health-related quality of life,  
44 and recovery self-efficacy. Time spent sitting and BMI significantly decreased for those  
45 completing the program.

## 46 **Conclusions**

47 Although significant benefits of physical activity were observed following a complete-case-  
48 analysis, results should be dealt with caution. Studies with a larger and less heterogeneous  
49 sample and robust study designs able to measure causal effects would be desirable.

## 50 **Trial registration**

51 German Clinical Trials Register (DRKS): Evaluation of an app-based activity intervention for  
52 statutory health insured people. DRKS-ID: DRKS00017392. (14 June 2019)

## 54 **Strengths and limitations of this study**

- 55 • The evaluation of the intervention is carried out under real-life conditions.
- 56 • Various approaches were used to describe the effects of the intervention.
- 57 • The small sample size, broad inclusion criteria for participation bias and a high dropout  
58 rate limit the internal validity.
- 59 • Due to its observational design and the absence of a control group and randomisation,  
60 this study can only provide limited data on how individual app components contributed  
61 to the overall effect of the app.
- 62 • Most data collected were based on self-assessment.

# 64 **INTRODUCTION**

## 65 **Background**

66 Non-communicable diseases are substantially caused by lifestyle-associated factors like  
67 insufficient physical activity [1]. In addition to non-communicable diseases, activity also  
68 influences quality of life and mental health [2]. To prevent chronic diseases like diabetes, it is  
69 recommended to promote physical activity across all age groups [3–6]. Effective strategies to  
70 increase motivation and reduce barriers for behaviour change require sustained efforts and  
71 ongoing support [7–9]. Behavioral change support by the use of smartphones in particular  
72 seems promising due to their widespread use and low barriers to participation uptake [10,11].

1 73 Smartphone app based interventions providing performance-related feedback, psychosocial  
2 74 networking and goal setting have been found to effectively increase physical activity [12–16].  
3 75 Furthermore, it has been widely described that increased self-efficacy can have positive  
4 76 effects on behavior change [17–19]. According to the Health Action Process Approach  
5 77 (HAPA), different subcomponents of self-efficacy can be distinguished [20]. Particularly  
6 78 decisive is the stability respectively variability of the subcomponents in the present study.  
7 79 Digital interventions have the unique potential to combine these effective strategies while  
8 80 keeping user acceptance high [21,22].  
9 81

10 82 Despite these known components of successful behavior change, the generation of evidence  
11 83 in the field of digitally supported behavior change predominantly focused on apps developed  
12 84 in relation to scientific studies, rather than evaluating freely accessible apps [23,24]. As a  
13 85 result, despite the increasing number of health apps on the market, the minority of them is  
14 86 based on strong empirical and scientific evidence [10,25–28]. Scientific evaluations of  
15 87 available apps offer great potential for improving both present and future apps [29–31]. While  
16 88 studies show promising results on the effectiveness of these interventions to prevent [32] or  
17 89 successfully manage [6,33] chronic lifestyle-related diseases, e.g. by using videos for  
18 90 preventive purposes,[34] the strategies needed to achieve sustainable behavior change seem  
19 91 to have received little attention [12].

20 92 Reasons for the described limited evidence base of digital health apps include methodological  
21 93 challenges during evaluation. In order to guide evidence-based decision making, RCTs are  
22 94 regarded as highest level [35]. However, digital health interventions usually comprise multiple  
23 95 components and are mostly designed as modular interventions offering tailored as well as  
24 96 performance-based adaptations or feedback [36]. This may end up in circumstances where  
25 97 RCTs may not be feasible. As such, challenges including randomization, timing of  
26 98 assessment, acceptance by patients and physicians, blinding, as well as defining control  
27 99 groups and relevant endpoints need to be considered [37]. In addition to the described  
28 100 challenges during evaluation, limited guidance is available on the mid- to long term outcomes  
29 101 [38,39].

30 102 Therefore, the primary objective of this study was to investigate the effect of the video-based  
31 103 and freely on the market available smartphone app ('VIDEA bewegt') over eight program  
32 104 weeks on physical activity (MET-minutes per Week and steps per day) in German adults.  
33 105 Secondary objectives were to analyse the associated changes in self-efficacy and health-  
34 106 related quality of life.  
35 107

## 36 108 **Hypotheses**

37 109 The users of 'VIDEA bewegt' who participate in the study increase their average daily step  
38 110 count and achieve a higher number of metabolic equivalent (MET) minutes per week, a

111 significantly higher health-related quality of life, a significantly higher motivational,  
112 maintenance and recovery self-efficacy after the first four weeks, and after completion of the  
113 eight-week course, compared to the beginning of data collection.

## 114 115 **MATERIALS AND METHODS**

116  
117 A detailed study protocol following important recommendations formulated by Eysenbach and  
118 the CONSORT-EHEALTH Group [40] was published prior to the data analysis [41].

### 119 120 **Study design and summary of intervention**

121 Data collection took place from July 2019 to July 2020. The evaluation of the app 'VIDEA  
122 bewegt' is designed as a single-arm observational study, assessing the app's effectiveness  
123 and usability under real-life conditions. The smartphone app 'VIDEA bewegt' is a video-based  
124 program to increase physical activity in everyday life. The app is divided into eight program  
125 weeks, each of which follows a consistent structure. The core of the app are four videos per  
126 program week. Theoretical videos explain and illustrate the importance of exercise and  
127 lifestyle, as well as ways to build up motivation. Practical videos present exercises to improve  
128 strength and endurance in a way which can be followed without the use of supplies.  
129 Additionally, motivational components such as goal setting, progress documentation, and  
130 personal messages are included. More extensive information can be found in the study  
131 protocol [41].

### 132 133 **Setting**

134 'VIDEA bewegt' is an app enabling users to access educational content via their smartphone  
135 anywhere and at any time. It was made available on the German market for Android and iOS  
136 in March 2019. Costs of the program are partially reimbursed by health insurance companies.  
137 Further information can be found on the German website <https://videabewegt.de> [42].

138 A clinical visit or in-person contact with a physician or diabetes specialist was not required.  
139 However, it was possible to consult experts in preventative health care and sports science via  
140 an integrated chat function. Problems could also be discussed with other users and experts in  
141 a forum.

### 142 143 **Participants**

144 To register in the app, interested individuals had to be of legal age ( $\geq 18$  years old) and declare  
145 that they were free of serious medical conditions such as heart failure. All registered  
146 individuals were invited to the study without further restriction.



## 148 **Patient and public involvement**

149 Potential participants were included in pretesting the questionnaires in order to assess their  
150 logic, understandability, and technical performance. A usability test with ten individuals  
151 provided insight in strengths and weaknesses of the app. Additionally, all study participants  
152 were asked to answer questions regarding their experience with the app's components. All  
153 data that made it possible to further optimize the app was forwarded to the developing  
154 company.

## 156 **Procedure**

157 App users interested in the study received an email and access to the first online  
158 questionnaire, which included the consent form and privacy policy. Individuals who completed  
159 the first questionnaire became study participants and received further questionnaires after  
160 completion of the fourth and eighth program weeks. In addition, internal app usage data  
161 including step counts were collected. For the analysis, three relevant time points were defined  
162 at which the individual outcome variables would be compared. The program start defined the  
163 time point T0, the program half the time point T1 and the program completion the time point  
164 T2. Participants received an email with a link to the online questionnaire at each time point.  
165 As such, data collection depended on participants' program usage. If a questionnaire was not  
166 completed after two days, the participants received a reminder. The study was conducted  
167 entirely digitally.

## 169 **Outcomes**

170 *Primary outcomes* were physical activity based on MET minutes per week (metabolic  
171 equivalent) and step numbers.

172 *Secondary outcomes* included physical self-efficacy (motivational, maintenance, recovery  
173 self-efficacy), health-related quality of life: MCS (mental health component summary score)  
174 and PCS (physical health component summary score).

175 To measure the outcome variables, validated self-reporting measurement instruments were  
176 applied. The Global Physical Activity Questionnaire (GPAQ) was used to record MET minutes  
177 per week as well as sedentary time per day [43,44]. The assessment of health-related quality  
178 of life is based on the SF-8 questionnaire [45,46]. Self-efficacy was measured in the three  
179 dimensions of motivation self-efficacy, maintenance self-efficacy and recovery self-efficacy  
180 [47,48]. For each of these three dimensions, statements were phrased in a questionnaire to  
181 which agreement was indicated using a Likert scale. Objective measurements of step counts  
182 were used. As a source of these step counts, users could either synchronize an external  
183 pedometer with the app or capture steps with their smartphone. For the comparison between  
184 T0 and T2, all persons were included who had entered their steps on at least 5 of 14 days at

1 185 both start and end of the program. For the comparison between T0 and T1, all persons who  
 2 186 had entered their steps on at least 3 of 7 days were included.  
 3 187

4 187

## 6 188 **Statistical analyses**

7 189 Sociodemographic data and user behaviour were analysed descriptively. The Shapiro-Wilk-  
 8 190 Test was used to test for normal distribution. The hypotheses were tested using a one-sided  
 9 191 Wilcoxon-Test for dependent samples at T0, T1 and T2 due to lack of normal distribution. A  
 10 192 subgroup analysis was not conducted on account of the small sample size. Due to the  
 11 193 exploratory nature of the data analysis, Bonferroni correction was omitted [49,50]. Instead, an  
 12 194 exploratory analysis was added to separate individuals who completed the program and who  
 13 195 showed an increase in activity.

14 196 Average values were calculated for the number of steps per day. For the comparison of T0  
 15 197 and T2, all persons were included who synchronized steps on at least 5 of 14 days at the  
 16 198 beginning and end. For the comparison of T0 and T1, persons with at least three out of seven  
 17 199 days of synchronization were included following the same method.

18 200 The analysis was conducted as a complete case analysis.  
 19 201

20 201

## 21 202 **RESULTS**

22 203

### 23 204 **Description of the sample**

24 205 During the data collection period, 1519 individuals registered with the app. Of those, 103  
 25 206 individuals (6,8%) followed the study invitation and completed the first questionnaire. Two  
 26 207 people withdrew their participation during the survey, and four people were excluded from the  
 27 208 analysis because of not completing the first questionnaire at the beginning of program use.  
 28 209 Consequently, 97 people were included in the data analysis, 55 of whom successfully  
 29 210 completed the program and all questionnaires (see Table 1).  
 30 211

31 211

32 212 *Table 1 Characteristics of the study population*

Overall n	97
Age mean (SD) in years	47.52 (13.52)
Sex	80 female (82%), 17 male (18%)
Body-Mass-Index median (IQR) in kg/m <sup>2</sup>	26.26 (8.8)
Marital status	
Married	57
Living in stable relationship	15
Divorced, separated	10
Single	11

Widowed	3
Other	1
Level of education	
completed professional training	32
degree from university	35
high school	14
secondary school	13
other	4
Gainful employment	
full-time	49
half-time	16
retired	16
part-time employed	7
not employed	9
Other Sports courses <sup>1</sup>	
Yes	49
No	48
Other Health apps <sup>2</sup>	
Yes	30
No	67

Notes. 1 = Participation in sports courses, 2 = Use of other health apps in addition to the VIDEA program. SD=standard deviation, IQR=Interquartile range

215

216 The median duration of program use was 68 days (Interquartile range (IQR) 64 days). The  
217 female participants accounted for 82% of the participants.

218

### 219 **Comparison of persons with and without program completion**

220 A total of 42 out of 97 study participants had not completed the program, which resulted in 42  
221 (43%) incomplete datasets. Due to the proportion of missing data exceeding 40%, imputation  
222 methods were not used [51].

223 Comparing the groups of persons with and without program completion, age, gender  
224 distribution and marital status did not differ substantially. In the group with program completion,  
225 the proportion of persons with a university degree was larger. The proportion of full-time  
226 employees was smaller resulting in a larger proportion of retired persons. In the group with  
227 program completion, the proportion of people who used additional health apps was smaller.  
228 BMI was also lower here, while health-related quality of life and physical activity did not differ.

229

### 230 **Physical Activity**

231 The hypothesis that physical activity increases significantly between program start and  
 232 completion can be supported for self-reported MET minutes per week. In contrast, the  
 233 hypothesis that there is a significant increase in MET minutes already within the first half of  
 234 the program cannot be confirmed (see Table 2). For the number of steps per day, neither a  
 235 significant increase in the first half nor over the entire program time was detected.

236

237 Table 2 Primary outcome measures, using asymptomatic one-sided Wilcoxon-tests

	Median (IQR) n=55	T0 vs. T1	T1 vs. T2	T0 vs. T2
MET minutes per week	T0: 2400 (3140)	$z=-1.391$ , $p=0.082$ , $n=55$ , $r=0.188$	$z=-1.778$ , $p=0.038$ , $n=55$ , $r=0.240$	$z=-1.927$ , $p=0.027$ , $n=55$ , $r=0.260$
	T1: 2760 (4100)			
	T2: 2640 (5680)			
Steps per day	T0: 7043 (4347), n=27	$z=-0.470$ , $p=0.638$ , $n=31$ , $r=0.084$		$z=-1.562$ , $p=0.061$ , $n=27$ , $r=0.301$
	T2: 6829 (4878), n=27			

238 *IQR=Interquartile range, MET=metabolic equivalent, T0=program start, T1=program half, T2=program completion*

239

240 **Health related quality of life and Self-efficacy**

241 The hypotheses that health-related quality of life based on the Physical Component Summary  
 242 (PCS) and the Mental Component Summary (MCS) increases significantly in the first half of  
 243 the program and over the entire program period can both be confirmed. Looking at self-  
 244 efficacy, the formulated hypotheses can only be confirmed for recovery self-efficacy, where  
 245 there was a significant increase over the entire program period. In contrast, there were no  
 246 significant increases in motivational and maintenance self-efficacy (see Table 3).

247 Table 3 Primary outcome measures, using asymptomatic one-sided Wilcoxon-tests

	Median (IQR) n=55	T0 vs. T1	T1 vs. T2	T0 vs. T2
PCS	T0: 49.74 (13.06)	$z=-2.409$ , $p=0.008$ , $n=55$ , $r=0.325$	$z=-1.694$ , $p=0.045$ , $n=55$ , $r=0.228$	$z=-3.050$ , $p=0.001$ , $n=55$ , $r=0.411$
	T1: 51.80 (13.34)			
	T2: 50.14 (9.33)			
MCS	T0: 47.80 (12.17)	$z=-3.599$ , $p<0.001$ $n=55$ , $r=0.485$	$z=-0.537$ , $p=0.296$ , $n=55$ , $r=0.072$	$z=-3.484$ , $p<0.001$ , $n=55$ , $r=0.470$
	T1: 52.49 (8.09)			
	T2: 52.31 (9.56)			
motivational self-efficacy	T0: 3.67 (1.00)	$z=-0.528$ , $p=0.238$ , $n=55$ , $r=0.071$	$z=-0.421$ , $p=0.737$ , $n=55$ , $r=0.057$	$z=-0.125$ , $p=0.574$ , $n=55$ , $r=0.017$
	T1: 3.67 (1.16)			
	T2: 3.67 (1.66)			
maintenance	T0: 3.00 (1.00)	$z=-1.043$ ,	$z=-0.592$ ,	$z=-1.199$ ,

self-efficacy	T1: 3.00 (1.00)	$p=0.142$ , $n=55$ ,	$p=0.289$ , $n=55$ ,	$p=0.092$ , $n=55$ ,
	T2: 3.33 (1.33)	$r=0.141$	$r=0.08$	$r=0.162$
recovery self-efficacy	T0: 3.00 (0.84)	$z=-0.368$ ,	$z=-2.075$ ,	$z=-1.850$ ,
	T1: 3.67 (1.00)	$p=0.323$ , $n=55$ ,	$p=0.019$ , $n=55$ ,	$p=0.032$ , $n=55$ ,
	T2: 4.00 (2.00)	$r=0.05$	$r=0.28$	$r=0.249$

IQR=Interquartile range, PCS=Physical Component Summary Score, MCS=Mental Component Summary Score, T0=program start (baseline), T1=program half, T2=program completion

### Additional Analysis

In addition, to the main hypotheses described above, further calculations were performed using the data from the GPAQ and the general questionnaire.

In a first analysis, using only program completers with complete data sets ( $n=55$ ), the Body Mass Index (BMI) was analyzed, which decreased significantly over the entire program period and between T1 and T2. Furthermore, the time participants spend sitting per day decreased significantly between T0 and T2 as well as T1 and T2. In addition to calculating MET minutes per week, the GPAQ also allows for an analysis of separate activity dimensions (work, transportation, and leisure). The analysis showed that activity during leisure time increased significantly, while activity at work and in transportation did not change significantly (see Table 4).

Because a large proportion of participants already reported high values of MET-minutes per week ( $>4000$  MET-minutes per week) at T0 and were thus less likely to benefit from further increases in activity [52], the comparison between T0 and T2 was repeated for all individuals with baseline activity of less than 4000 MET-minutes per week. Results indicate a significant increase in activity for these participants with large effect sizes (see Table 4).

Table 4 – Additional analyses using asymptomatic two-sided Wilcoxon-tests

	Median (IQR)	T0 vs. T1	T1 vs. T2	T0 vs. T2
BMI in $\text{kg}/\text{m}^2$ , $n=55$	T0: 25.51 (8.45)	$z=-0.010$ ,	$z=-3.117$ ,	$z=-2.445$ ,
	T1: 25.95 (8.54)	$p=0.992$ ,	$p=0.002$ ,	$p=0.014$ , $r=0.330$
	T2: 24.91 (7.26)	$r=0.001$	$r=0.420$	
Time spent sitting in hours, $n=55$	T0: 6 (4)	$z=-0.420$ ,	$z=-2.962$ ,	$z=-2.472$
	T1: 6 (4)	$p=0.675$ ,	$p=0.003$ ,	$p=0.013$ , $r=0.333$
	T2: 5 (4)	$r=0.091$	$r=0.399$	
Active minutes in leisure time in minutes per day, $n=55$	T0: 25.71 (22.86)	$z=-3.053$ ,	$z=-1.171$ ,	$z=-2.898$ ,
	T1: 27.31 (30.00)	$p=0.002$ ,	$p=0.242$ ,	$p=0.004$ , $r=0.391$
	T2: 31.43 (51.43)	$r=0.412$	$r=0.158$	
Active minutes	T0: 12.86 (64.29)	$z=-0.314$ ,	$z=-0.403$ ,	$z=-1.559$ ,

at work, in minutes per day, n=55	T1: 21.43 (85.71)	$p=0.753,$	$p=0.687,$	$p=0.119, r=0.210$
	T2: 14.29 (100.00)	$r=0.042$	$r=0.054$	
Active minutes in transport, in minutes per day, n=55	T0: 21.43 (40.00)	$z=-0.669,$	$z=-1.789,$	$z=-0.510$
	T1: 21.43 (24.29)	$p=0.503,$	$p=0.074,$	
	T2: 17.14 (31.43)	$r=0.090$	$r=0.241$	$p=0.610, r=0.069$
MET-minutes per day of people with initial activity <4000 MET-Minutes per day, n=41	T0: 1640 (1780)	$z=-3.882,$	$z=-1.109,$	$z=-3.039,$
	T1: 2560 (2756)	$p<0.001,$	$p=0.267,$	
	T2: 2160 (2510)	$r=0.606$	$r=0.173$	$p=0.002, r=0.475$

IQR=Interquartile range, BMI=Body Mass Index, MET= metabolic equivalent, T0=program start, T1=program half, T2=program completion

## DISCUSSION

The primary aim of this study was to assess the effects of the video-based smartphone app 'VIDEA bewegt' on physical activity and related outcomes in German adults under real-life conditions. Individuals who completed the program experienced a significant increase in physical activity based on several parameters and health-related quality of life. Furthermore, the recovery self-efficacy increased significantly as well.

Data was collected from 97 study participants to provide the basis for the conducted study. Women accounted for more than three-quarters of the sample. It is known that women tend to be more interested in health interventions than men and are easier to convince of new interventions [53,54]. Additionally, well-educated people often have a greater interest in health interventions. It is therefore not surprising that the study mainly involved people who had completed their education and were in full-time employment [54].

**Effectiveness:** The 55 subjects with program completion reported a median physical activity of 2400 MET minutes per week at T0. For people in Germany, a representative study determined an average value of 630 MET minutes per week [55]. Consequently, the sample was physically active to an above-average degree. Insufficient physical activity is defined by the WHO as less than 600 MET minutes per week [56]. However, it is known that physical activity should be much higher in order to effectively reduce risks of chronic diseases [52]. Despite the relatively high baseline physical activity levels of the sample, participants completing the program showed improvements of physical activity measured by MET-Minutes

per week (significant increase T0/T2 and T1/T2 with  $r=0.260$  and  $r=0.188$ ). Including only those individuals with less than 4000 MET minutes per week at baseline, this increase was significant with medium and strong effect sizes ( $r=0.475$  and  $r=0.606$ ). For this part of the sample, MET minutes per week increased by 32%. Similar rates of activity increase were also found in other studies [10,15].

Step counts per day are a widely used measure of physical activity [57]. However, only few and incomplete data sets were available in the present study, which is why results have to be dealt with caution. The step count data sets did not show any significant increases in the number of steps per day. It would have been desirable to compare the objective step counts with the less objective MET minutes, as recommended [58]. However, since only 27 of 55 people synchronized their steps at the beginning and end of the program on at least five of 14 days, no such comparison was made.

Sedentary time per day decreased significantly from a median of six to five hours. In fact, five hours of sedentary time were found to be the average of the German population [59]. While total mortality is significantly reduced by replacing one hour of sedentary time with activity [60], the decrease in sedentary time observed in the study can be interpreted as clinically relevant. The median BMI of the 97 study participants of  $26.26 \text{ kg/m}^2$  at baseline is comparable to similar studies [10,15,61]. It significantly decreased with medium effect size ( $r=0.330$ ) between T0 and T2 for the 55 individuals with program completion. As such, while the median BMI lied in the range of overweight ( $>25 \text{ kg/m}^2$  [62]) at baseline, participants completing the program improved to ranges of normal weight ( $<25 \text{ kg/m}^2$ ) after eight program weeks with individually different time periods being needed (median program use of 68 days). Considering weight changes as the basis of BMI values, clinically relevant weight decreases of at least 5% were found in 7 of 55 subjects [63].

Health-related quality of life increased significantly in the first half of the program, but also over the entire program period, with a medium effect size. In 2004, norm values of PCS=50.30 and MCS=53.25 were determined for the German population [64]. In the PCS, the number of people above the norm did not change and remained at 27/55. In the MCS, only 12/55 people were above the norm at the beginning of the program and 25/55 at the end of the program. Overall, however, the health-related quality of life could not be rated as above average, since the medians were below the norm at all time points. A clinically relevant change in PCS or MCS of at least three points [65] was found in the PCS for 27/55 subjects and in the MCS for 37/55 subjects.

While motivational and maintenance self-efficacy did not change during the intervention, there was a significant increase in recovery self-efficacy for individuals completing the program (recovery self-efficacy  $r=0.249$ ). Luszczynska et al. demonstrated that recovery self-efficacy has a stronger predictive influence on physical activity than maintenance self-efficacy [66]. Based on the health action process approach (HAPA), these findings seem conclusive, as

1 330 recovery self-efficacy is particularly important for the implementation and execution of new  
2 331 behavior [67]. The increase of recovery self-efficacy emerged between T1 and T2, while the  
3 332 comparison between T0 and T1 did not show an increase. It is known that recovery self-  
4 333 efficacy is especially important in later stages of behavior change when barriers and failures  
5 334 occur, with overcoming such setbacks being the main challenge. High recovery self-efficacy  
6 335 also is important for resuming health-promoting behaviors after an interruption [66]. In this  
7 336 present study, the rather informal character as well as participants' freedom to execute the  
8 337 whole program resulted in heterogeneous intervention durations. Thus, individuals who  
9 338 successfully completed the intervention may have been particularly effective at coping with  
10 339 such interruptions. It is possible that the positive learning experiences contributed to an  
11 340 improvement in recovery self-efficacy, as well.

12 341 For digital interventions, the correlation of high self-efficacy with high exercise frequency and  
13 342 an increase in health-related parameters is well known [68]. For example, it has already been  
14 343 described that self-efficacy increased during an intervention to reduce BMI [69]. The results of  
15 344 the present study confirm the important role of self-efficacy in digital interventions. Accordingly,  
16 345 the specific relevance of each dimension of self-efficacy as well as the maintenance of  
17 346 behavior changes reflected by mid-to-long-term follow-ups should be addressed in future  
18 347 studies. Research on self-efficacy may help to develop more effective and better  
19 348 individualizable interventions.

20 349  
21 350 *Dropouts:* The fraction of people responding to a study invitation is often less than ten percent  
22 351 [70]. In the present study, 6.8 percent of the app users became study participants. Of the 97  
23 352 people included in the analysis, only 55 completed the program. It is known that loss of  
24 353 interest, hidden costs, or complicated use can be responsible for dropout [71]. The sample  
25 354 covered an age range of 22-75 years and had a mean age of 48 years. Similar age averages  
26 355 can also be found in other studies [10,15,61]. An analysis of individual subgroups would have  
27 356 been desirable, but would have required a larger sample [72].

### 28 357 29 358 **Limitations**

30 359 An important strength of this study is that it was conducted under real-life conditions. Another  
31 360 strength is the user-centered study design, in which potential users were involved in the design  
32 361 of the questionnaires and the app [73].

33 362 However, the following limitations of our approach should be taken into account. Most of the  
34 363 data collected is based on self-assessment during an app use in real life. The missing  
35 364 possibility to validate collected data is a well-known problem in the evaluation of digital  
36 365 interventions [74]. The number of app users remained below expectations, resulting in a small  
37 366 sample that did not allow for subgroup analysis. Though the sample size can be regarded as  
38 367 small, it is comparable to other projects [12].



1 368 Voluntary study participation may have resulted in a selection bias, with primarily participation  
2 369 of highly motivated individuals [75]. Of these individuals, only those with program completion  
3 370 were analyzed in the complete case analysis, which entails a potential overestimation of  
4 371 positive effects [76]. Compared to those who did not complete the program, these individuals  
5 372 used other health apps less frequently and had a lower BMI. Therefore, it is likely, that  
6 373 especially individuals who previously had little app experience completed the program.  
7 374 Furthermore, a financial incentive was offered for study participation through reimbursement  
8 375 of program costs, which may also have influenced the sample composition [70].  
9 376 Broad inclusion criteria with only limited restrictions caused an inhomogeneous study  
10 377 population, in terms of individual characteristics such as age, BMI and baseline activity. This  
11 378 is matched by the fact that many results show wide interquartile ranges and can be considered  
12 379 as inconsistent. Due to its observational design, the absence of a control group and missing  
13 380 randomisation, this study can only provide limited data on how individual app components  
14 381 contributed to the overall effect of the app. This is relevant as the investigated app can be  
15 382 defined as a complex intervention entailing multiple components. In addition, the observational  
16 383 study design did not allow for controlling potential confounders relating to the use of additional  
17 384 apps in parallel to study participation. Thus, the small sample size made it difficult to account  
18 385 for confounding factors during data analysis. Additionally, it was not possible to conclusively  
19 386 clarify which individuals could benefit most from app use.  
20 387 The app was regularly updated by the responsible company during the period of data  
21 388 collection, without changing any essential content. Nevertheless, small changes of the design,  
22 389 or the app performance could have led to different display of the content.  
23 390 Additionally, the time of completing questionnaires was based on the program duration which  
24 391 substantially differed between participants. This is in line with the approach of a pragmatic  
25 392 study but may have introduced a risk of measurement bias affecting internal validity  
26 393

## 394 **Outlook**

395 While most apps for increasing physical activity focus on documenting activity,[12,77] "VIDEA  
396 bewegt" offers a novel concept in which video-based information, practical guidance and  
397 helpful tips are provided. Such interventions are particularly in demand at times of the  
398 Coronavirus disease (COVID-19) pandemic to counteract restricted activity through lockdown  
399 policies,[78] minimizing the risk of severe Coronavirus disease (COVID-19) [79]. The results  
400 of the one-year follow-up are still awaited, which will clarify the important question of the  
401 sustainability of observed effects. With special regard to the described limitations of this study,  
402 future projects should aim for a larger sample to allow for subgroup analyses. At the same  
403 time, the proportion of missing data should be minimized by including a less heterogeneous  
404 sample. In addition, a more direct way to contact the participants should be considered. The  
405  
406

1 405 quality of the results would also benefit from data collection methods not solely based on self-  
2 406 reported values.

3 407

## 4 408 **Conclusion**

5 409 Although significant benefits of physical activity were observed following a complete-case-  
6 410 analysis after eight program weeks, results should be dealt with caution. Using “VIDEA  
7 411 bewegt” resulted in an increase of physical activity for some participants. As such, significant  
8 412 increases in MET minutes per week and health-related quality of life as well as significant  
9 413 decreases in time spent sitting and BMI were reported by program completers. Overall, the  
10 414 combination of educative strategies, video-based exercise tutorials and motivational support  
11 415 seemed promising. Future research is warranted to evaluate the effectiveness of the whole  
12 416 program using rigorously conducted trials while enrolling a larger number of participants.

13 417

## 14 418 **ETHICS AND DISSEMINATION**

15 419

### 16 420 **Ethics approval**

17 421 After an ethics application was submitted to the Ethics Committee of the Technical University  
18 422 of Dresden on 12 April, the Ethics Committee approved the study on 25 May 2019 (EK  
19 423 272062019).

### 20 424 **Consent to participate**

21 425 The informed consent to participate is obtained written by clicking a button in the first online  
22 426 questionnaire in accordance with the DSGVO as a prerequisite for participation

23 427

## 24 428 **STATEMENTS**

25 429

### 26 430 **Authors' contributions**

27 431 TF and PS wrote the manuscript, collected the data, and performed the data analysis. TF  
28 432 focused on the analysis on physical activity, health-related quality of life, and the exploratory  
29 433 analysis, while PS focused on self-efficacy. PEHS advised and provided feedback and  
30 434 reviewed the manuscript. PT regularly provided feedback on the overall study flow and  
31 435 participated in the writing of the manuscript. All authors reviewed and approved the final  
32 436 version of the manuscript before submission.

33 437

### 34 438 **Competing interests**

35 439 The principal investigator Prof Schwarz was involved in the development and implementation  
36 440 of the app ‘VIDEA bewegt’ as a medical expert.

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1 441 He is responsible for the medical and theoretical background and is shown in the app's videos.  
2  
3 442 He received no payment for his participation in the app.  
4  
5 443

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12  
13 449

## 16 450 **Data availability**

17 451 Data are available upon reasonable request.

18 452 Individual participant data collected during the trial will be available after  
19 453 deidentification and completion of data collection.

20 454 Data will be shared with researchers who provide a methodologically sound  
21 455 proposal. Proposals should be directed to peter.schwarz@uniklinikum-dresden.de.

22 456 To gain access, data requestors will need to sign a data access agreement.  
23  
24 457

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## STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1-2
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2-3
Objectives	3	State specific objectives, including any prespecified hypotheses	3
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	4
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	5
Bias	9	Describe any efforts to address potential sources of bias	5
Study size	10	Explain how the study size was arrived at	6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5-6
		(b) Describe any methods used to examine subgroups and interactions	
		(c) Explain how missing data were addressed	
	6	(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	7

Continued on next page

<b>Results</b>			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6
		(b) Give reasons for non-participation at each stage	6
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	6-7
		(b) Indicate number of participants with missing data for each variable of interest	7
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	7
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7-8
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	10
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	12-13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13-14
Generalisability	21	Discuss the generalisability (external validity) of the study results	14
<b>Other information</b>			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	14-
			15

\*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at [www.strobe-statement.org](http://www.strobe-statement.org).