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The effect of bright light therapy on depressive symptoms in adults with intellectual disabilities: Results of a multicentre randomized controlled trial

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Abstract

Background: Although a large number of adults with intellectual disabilities have depressive symptoms, non-pharmacological treatments are scarce. The present authors investigated whether bright light therapy (BLT) is effective in decreasing depressive symptoms compared to care as usual.

Methods: This multicentre randomized controlled trial consisted of three study groups (10,000 lux BLT, dim light BLT and a no-BLT group). Participants received BLT for 30 min in the morning (14 consecutive days), additional to their regular care. Primary outcome was as follows: depressive symptoms measured with the ADAMS Depressive Mood subscale 1 week after the end of BLT (same time period in the no-BLT group).

Results: Forty-one participants were included in our trial. In both BLT groups, a significant decrease in depressive symptoms was seen. No significant differences were found between 10,000 lux BLT and no-BLT (p = .199) and no significant differences between dim light BLT and no-BLT (p = .451). A minimum amount of side effects and no adverse events were reported.

Conclusions: In both BLT interventions, a decrease in depressive symptoms was seen. With 10,000 lux BLT, depressive symptoms decreased even below the clinical cut-off point, which makes BLT a promising intervention for clinical practice.

KEYWORDS

bright light therapy, depressive symptoms, intellectual disabilities, randomized controlled trial

1 | INTRODUCTION

Depression is common in the general population and has a large impact on functioning in daily life (Wittchen et al., 2011). Compared to the general population, even higher numbers of depression and depressive symptoms are found in the population of adults with intellectual disabilities (Cooper, Smiley, Morrison, Williamson, & Allan, 2007; Hermans, Beekman, & Evenhuis, 2013). Despite the large number of adults with intellectual disabilities and depressive symptoms, treatment options, especially for those with severe intellectual disabilities, are scarce

(Hamers, Festen, & Hermans, 2018). Some adults with mild or moderate intellectual disabilities and without major verbal limitations may benefit from psychological interventions, for example cognitive behavioural therapy (CBT) (Vereenooghe & Langdon, 2013), but a large part of adults with intellectual disabilities and depressive symptoms get pharmacological treatment or no treatment at all. Pharmacological side effects, high numbers of polypharmacy, the lack of non-pharmacological interventions for those with severe intellectual disabilities, together with the high prevalence of depressive symptoms in adults with intellectual disabilities, make investigating other non-pharmacological interventions extremely important.

1.1 | Bright light therapy

In the general population, bright light therapy (BLT) is broadly studied and used in clinical practice to treat seasonal affective disorder and non-seasonal depression (Even, Schroder, Friedman, & Rouillon, 2008; Golden et al., 2005; Lieverse et al., 2011; Martiny, 2004; Nussbaumer et al., 2015; Tuunainen, Kripke, & Endo, 2004). The working mechanism is not fully understood, but it is suggested that disturbances in the circadian rhythms are involved (Germain & Kupfer, 2008; Monteleone, Martiadis, & Maj, 2011; Wirz-Justice, 2006). Our main biological clock, which controls our circadian rhythms, is situated in the hypothalamus in the suprachiasmatic nucleus (SCN). Retinal light input is the main influencer of the biological clock (Wirz-Justice, 2006). Neural pathways from the SCN lead to the pineal gland where melatonin is produced. In this way, light can influence the secretion of melatonin: when the amount of light increases, the production of the hormone melatonin is decreased (Griefahn, Kuenemund, & Robens, 2006). The effect of BLT is comparable to those of pharmacological interventions to decrease depressive symptoms (Golden et al., 2005), and BLT can even be more effective when combined with antidepressants (Lam et al., 2016). Besides, BLT seems to be a safe intervention without major side effects (Brouwer et al., 2017; Kogan & Guilford, 1998; Meesters & Letsch, 1998).

Unfortunately, the results of BLT studies in the general population cannot be generalized to the population of adults with intellectual disabilities, because many adults with intellectual disabilities have some kind of brain damage that might interfere with the above-mentioned neural pathways, for example congenital brain damage, progressive brain damage or damage caused by traumatic injury. Furthermore, a large amount of adults with intellectual disabilities are care-dependent and have physical and/or mobility problems. Therefore, it is possible that they benefit less from direct daylight because they do not spend the same amount of time outside compared to the general adult population.

In the intellectual disability population, BLT did not get much attention yet. Since 1998, some case reports were published (Altabet, Neumann, & Watson-Johnston, 2002; Cooke & Thompson, 1998; Tsiouris, 2007). These first explorations of BLT in the intellectual disability population showed promising results. However, systematic report of the results and control groups were lacking. A feasibility study in the Netherlands showed that BLT is a feasible intervention for adults with intellectual disabilities. Besides, they found a decrease in depressive symptoms after BLT in almost all patients, and in nearly half of the sample, a clinical relevant improvement was found (Hermans, Soerokromo, & Evenhuis, 2017). As larger studies with control groups are needed to expand the knowledge of the effect of BLT in the intellectual disability population, the primary objective of our study was to investigate whether BLT is effective in decreasing depressive symptoms in two BLT intervention groups compared to no-BLT (control group). Our secondary objective was to examine whether there is a significant difference in the effect of BLT between the two BLT intervention groups. Besides, we examined whether the effect of BLT is still visible 4 weeks after the end of BLT.

2 | METHOD

2.1 | Participants

Potential participants were recruited in three large care provider centres in the Netherlands that are part of the Healthy Ageing and Intellectual Disabilities Consort (HA-ID Consort). Physicians, psychologists and behavioural scientists of the care provider centres selected potential participants and decided whether a potential participant was able to understand the information of the study and to make the decision to give informed consent for participation. If the participant was not able to decide, the legal guardian was informed and gave written consent. Recruitment and inclusion of the participants started in May 2015 and ended in September 2017. The data collection ended in November 2017.

2.2 | Inclusion and exclusion criteria

Adults with intellectual disabilities (IQ ≤ 70) and with depressive symptoms were included in this study. To be included, a minimum score of 14 (clinical cut-off point) was needed on the Depressive Mood subscale of the Dutch version of the Anxiety, Depression And Mood Scale (ADAMS; range 0–39) (Hamers, van Ool, et al., 2018; Hermans & Evenhuis, 2013). Exclusion criteria were checked by a physician and behavioural scientist who were involved with the care of the participant. Exclusion criteria were as follows: a diagnosis of bipolar disorder, prepartum and/or post-partum depression, dementia, current delirium, hypomanic, current manic or psychotic episode, current suicidal behaviour or suicidal expressions and aphakia (the lens of the eye is missing). In addition, because of possible side effects in combination with BLT, the physician excluded participants who used specific photosensitizing medications and had recent eye surgery or certain diseases, for example porphyria and urticaria solaris. Previous BLT sessions must have ended more than 4 weeks prior to the inclusion.

2.3 | Ethical regulation and trial registration

Written informed consent was retrieved from each participant or from their legal guardian if the participant was not able to decide for himself due to the intellectual disabilities. The study did not interfere with the usual care and treatment of the participants. Ethical approval for all three care provider centres was given by the Ethics Committee of the Erasmus University Medical Centre Rotterdam in the Netherlands. Guidelines of the Declaration of Helsinki (64th WMA General Assembly, October 2013) were followed. Besides, this study is registered prior to the start of the study (NTR number: NTR5162) and CONSORT guidelines regarding Randomised Trials of Nonpharmacologic Treatments were followed (Boutron, Altman, Moher, Schulz, & Ravaud, 2017).

2.4 | Study design

2.4.1 | Randomization and masking

We conducted a multicentre randomized controlled trial (RCT) with three study groups to investigate the effect of BLT in adults with depressive symptoms. Block stratification was used to ensure that participants were properly distributed over the three study groups within each of the three participating centres. Block stratification was performed by a computerized program developed by an independent data manager. One researcher (PH) enrolled the participants and used the outcomes of the digital randomization to assign the participants to the right group. To ensure blinding of the researchers, lightboxes were coded before the start of the study by an independent researcher. Furthermore, the researchers and the professional staff were not informed about which type of lightbox was distributed to the participants. The participants and their professional caregivers were not blinded and were told that two lightboxes with different amount of lux were tested in the current study. They were instructed not to share details of the lightboxes and the amount of lux with the researchers. Participants living together at the same residence did not get BLT at the same time. When data collection was finished, the blinding was broken. No changes to methods were made after trial commencement.

2.4.2 | Sample size

Prior to this study, the ideal sample size was calculated based on a clinically relevant difference of four points decrease on the Depressive Mood subscale of the Anxiety, Depression And Mood Scale (ADAMS) (Hermans & Evenhuis, 2013; Hermans, Jelluma, van der Pas, & Evenhuis, 2012). Details of the sample size calculation are previously published (Hamers, Evenhuis, & Hermans, 2017). Our aim was to include at least 57 participants in each group. Hence, a maximum of 171 participants would be included in our study. Unfortunately, after an inclusion period of almost two and a half years (May 2015–September 2017), the intended sample size was not reached. A large screening with the inclusion criteria of this study among adults with intellectual disabilities (>1,000 participants) in the three participating care provider centres from October 2016 to March 2017 revealed some potential participants, but did not give enough perspective to extent the inclusion period longer than September 2017. Detailed information of our study protocol and the different obstacles we faced in this study are published previously (Hamers et al., 2017).

2.4.3 | Intervention

Two intervention groups (10,000 lux and a dim light condition) were used in this study. The dim light condition can be considered as a "placebo" condition of an BLT intervention. We compared the results of the 10,000 lux intervention with the results of the dim light condition, to study a possible placebo effect. In group I, participants received BLT with a 10,000 lux bright white UV-filtered lightbox (Philips Energy lightbox, type HF3319), additional to their care as usual. Participants in group II received BLT with a bright white lightbox with on average 317 lux, additional to their care as usual. In group II, we used the same lightbox as in group I, but a LEE filter (no. 299) was installed. This heat-resistant filter did not change the colour of the light. On the outside, the two lightboxes looked the same when they were turned off. The participants in group III got no-BLT only care as usual (control group). Participants in the two intervention groups received 30-min BLT in the morning as early as possible after wake up (at least before 12 a.m.), for a period of 14 consecutive days. Usually, BLT was given during breakfast. Besides oral information, a detailed BLT manual with pictograms was given to the participant and the professional caregiver before the start of the intervention. The professional caregivers were asked to report adherence in a daily log. The distance between the participant and the lightbox was 20 cm (tape measures were distributed). A distance of 30 cm was only allowed when the 20 cm distance was not possible, for example because of wheelchair use. When a 30 cm distance was used, BLT was extended with 30 min per day according to the manual of the lightbox. The treatment distances in group I and group II were the same. The amount of lux of all lightboxes was measured by the Medical Technology Department of the Erasmus University Medical Center Rotterdam in the Netherlands with the use of a lux metre (Konica Minolta T-10A). The average amount of lux at 20 cm of the lightboxes used in group I was 11,214 lux (range 10,860–11,640) and in group II was 317 lux (range 297–329). At a distance of 30 cm, the average amount of lux of lightboxes type I was 7,122 lux (range 6930–7380) and the average amount of lux of lightboxes type II was 198 lux (range 188–209). The Medical Technology Department checked all lightboxes used in this trial on safety. Physicians, psychologists and behavioural scientists were asked, but not obligated, not to make changes in (medication) treatment 4 weeks prior to enrolment up to 6 weeks after the end of the intervention if this was not

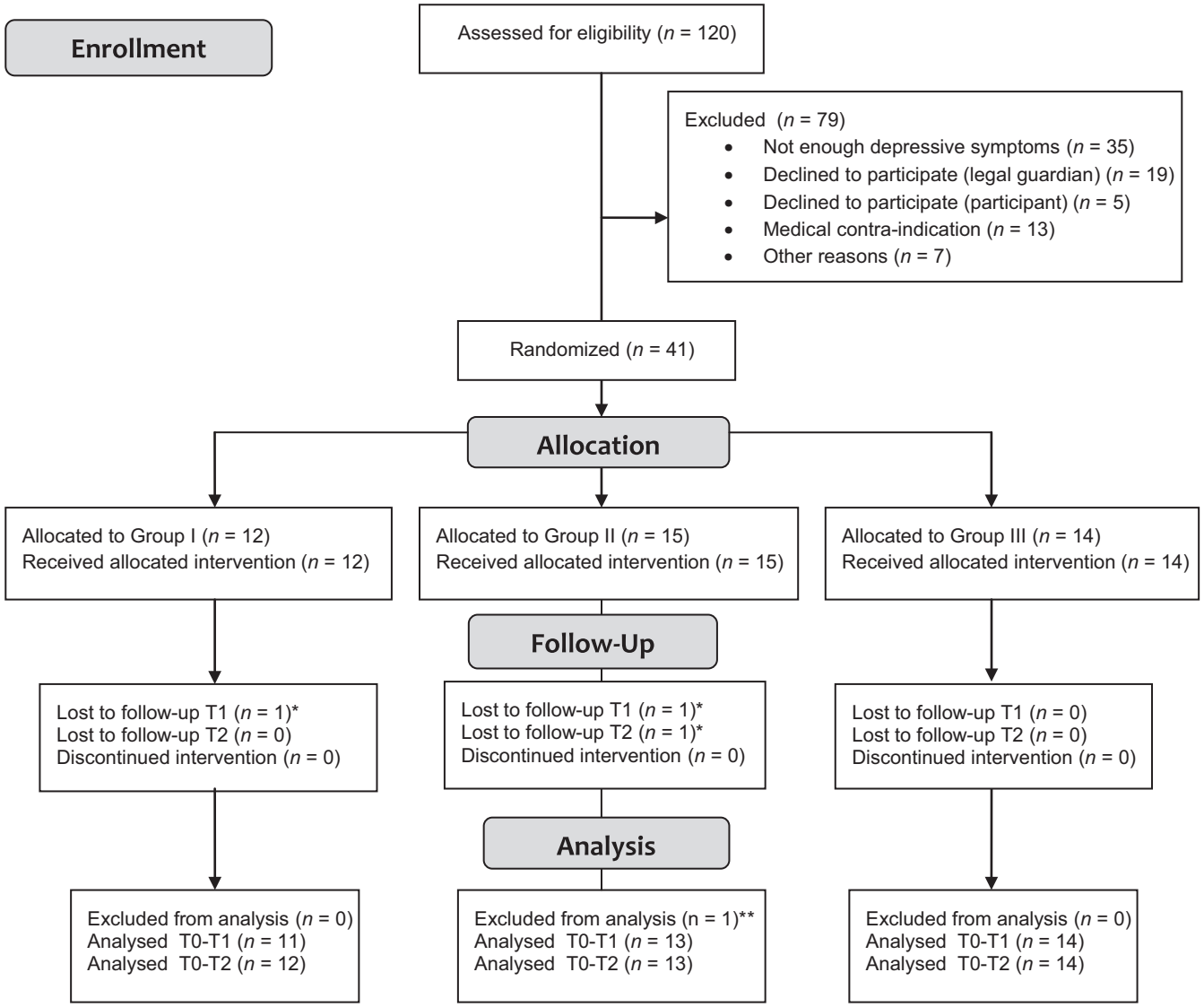

FIGURE 1 Flow diagram participants. *Professional caregiver did not complete the questionnaires at this time point. **No compliance to the study protocol

considered necessary. Caregivers were asked to report changes in treatment during the study.

2.4.4 | Objectives and outcomes

The primary objective of this study was to examine whether BLT is effective in decreasing depressive symptoms in two BLT intervention groups compared to no-BLT 1 week after the end of BLT. The Depressive Mood subscale (13 items) of the Anxiety, Depression And Mood Scale (ADAMS) was used to study these depressive symptoms prior to BLT (baseline, T0) and 1 week after BLT (T1) (Hamers, van Ool, et al., 2018; Hermans & Evenhuis, 2013; Hermans et al., 2012). The measurements in the control group (no-BLT) had the same frequency. The Depressive Mood subscale of the ADAMS consists of the following 13 items: "Sleeps more," "Depressed," "Sad," "Worried," "Attention," "Fatigued," "Lacks energy," "Distracted," "Facial expression," "Starting routine tasks," "Listless," "Trembles" and "Tearfull" (Hamers, van Ool, et al., 2018; Hermans & Evenhuis, 2013; Hermans et al., 2012).

Our secondary objectives were to examine whether there is a significant difference in effect of BLT between both intervention groups. The ADAMS Depressive Mood subscale scores on T0 and T1 of group I and group II were used to investigate this objective. Further, we examined whether the effect of BLT is still visible 4 weeks after the end of the BLT intervention with use of the Dutch ADAMS Depression subscale scores of groups I and II at T0 and T2. Additionally, subgroup analyses were used to examine depressive symptoms in the three different groups on T1 and T2.

In addition to the ADAMS Depressive Mood subscale, the Dutch Signalizing Depression List for people with Intellectual Disabilities (SDL-ID) (Roeden, 1989) was used to evaluate the effectiveness of BLT as well, because this measurement contains items that are

TABLE 1 Participant characteristics

	Group IBLT 10,000 lux *n* = 12	Group II BLT dim light *n* = 14	Group III Control group *n* = 14	*p*-value[a]
Sex				
Male (%)	5 (41.7)	4 (28.6)	11 (78.6)	**.024**
Female (%)	7 (58.3)	10 (71.4)	3 (21.4)	
Age, years				
Mean (*SD*)	56.17 (11.33)	57.14 (11.41)	52.07 (14.29)	.531
Level of intellectual disabilities (%)				
Mild	5 (41.7)	2 (14.3)	2 (14.3)	.076
Moderate	2 (16.7)	2 (14.3)	8 (57.1)	
Severe	3 (25.0)	7 (50.0)	2 (14.3)	
Profound	2 (16.7)	3 (16.7)	2 (14.3)	
Medication use (%)[b]				
Antidepressants	6 (50.0)	6 (42.9)	6 (42.9)	.728
Antipsychotics	9 (75.0)	9 (64.3)	8 (57.1)	.650
Benzodiazepines	4 (33.3)	5 (35.7)	3 (21.4)	.653
Anti-epileptics	5 (41.7)	4 (28.6)	2 (14.3)	.404
Contraception	2 (16.7)	2 (14.3)	1 (7.1)	.665
Beta-blockers	1 (8.3)	0 (0.0)	1 (7.1)	.540
Anxiolytics	0 (0.0)	0 (0.0)	0 (0.0)	.386
Melatonin	0 (0.0)	1 (7.1)	0 (0.0)	.440
No medication used	1 (8.3)	3 (21.4)	2 (14.3)	.596
Missing data	0 (0.0)	0 (0.0)	1 (7.1)	
ABC Irritability subscale				
Mean (*SD*)	9.17 (4.49)	10.36 (7.62)	12.00 (6.45)	.530
Total BLT days				
Mean (*SD*)	13.00 (1.54)	12.14 (2.07)	*n*.a.	.249
Date of BLT intervention/control group period, *n* (%)				
1st Quarter of the year	6 (50.0)	2 (14.3)	6 (42.9)	.164
2nd Quarter of the year	4 (33.3)	4 (28.6)	4 (28.6)	
3rd Quarter of the year	1 (8.3)	2 (14.3)	3 (21.4)	
4th Quarter of the year	1 (8.3)	6 (42.9)	1 (7.1)	

Abbreviations: ABC, the Aberrant Behavior Checklist; BLT, bright light therapy; ID, intellectual disability; *n*.a., not applicable; *SD*, standard deviation.

[a]Calculated as comparisons of the three groups, using ANOVA for continuous variables or chi-square tests for discrete variables. The comparison of total BLT days was only calculated for the two intervention groups.

[b]Some participants used more than 1 medication. Significant test values are in bold type.

complementary to the Dutch ADAMS Depressive Mood subscale. Besides, a subscale of the Aberrant Behavior Checklist (ABC) (Aman, Singh, Stewart, & Field, 1985) was used to measure "Irritability," because it is known that a large part of adults with intellectual disabilities and depressive symptoms have symptoms of irritability. In the Netherlands, these measurements are often used in clinical practice to evaluate the effectiveness of interventions. The questionnaires were completed by a professional caregiver at T0, T1 and T2. ABC scores were only available on baseline.

The presence of a major depression disorder according to the criteria of DSM-IV was investigated with the PAS-ADD Clinical Interview, which is a semi-structured psychiatric interview developed for adults with intellectual disabilities (Moss, 2011). Prior to the start of the study, the participants (if possible) and the

TABLE 2 Outcomes ADAMS Depression subscale and SDL-ID total score

	Group I 10,000 lux	Group II BLT dim light	Group III Control group
ADAMS Depression subscale T0			
Mean (*SD*)	21.83 (5.49)	19.86 (3.70)	19.43 (4.70)
ADAMS Depression subscale T1			
Mean (*SD*)	13.73 (5.68)[a]	16.00 (6.92)	18.86 (7.38)
ADAMS Depression subscale Change T0-T1			
Mean (95% CI)	8.36 (3.50 to 13.23)[b]	3.54 (0.82 to 6.26)[b]	0.57 (−3.91 to 5.05)
Cohen's *d* effect size T0-T1	1.52	0.73	0.10
(95% CI)	(−0.66 to 3.70)	(−1.26 to 2.72)	(−2.11 to 2.30)
ADAMS Depression subscale T2			
Mean (*SD*)	11.25 (7.03)[a]	14.85 (7.70)	16.29 (8.42)
ADAMS Depression subscale Change T0-T2			
Mean (95% CI)	10.58 (5.61 to 15.55)[b]	5.39 (2.13 to 8.64)[b]	3.14 (−1.62 to 7.91)
Cohen's *d* effect size T0-T2	1.75	0.87	0.48
(95% CI)	(−0.67 to 4.17)	(−1.29 to 3.04)	(−1.96 to 2.91)
SDL-ID total scores T0			
Mean (*SD*)	38.17 (6.63)	39.29 (3.41)	37.57 (6.16)
SDL-ID total scores T1			
Mean (*SD*)	30.82 (6.23)[a]	35.15 (6.14)	38.07 (7.98)
SDL-ID total scores Change T0-T1			
Mean (95% CI)	8.00 (3.43 to 12.57)[b]	4.00 (0.060 to 7.94)	−0.50 (−4.24 to 3.24)
Cohen's *d* effect size T0-T1	1.19	0.88	−0.07
(95% CI)	(−1.32 to 3.71)	(−0.91 to 2.66)	(−2.62 to 2.47)
SDL-ID total scores T2			
Mean (*SD*)	29.33 (5.94)[a]	32.69 (6.03)[a]	35.50 (7.62)
SDL-ID total scores Change T0-T2			
Mean (95% CI)	8.83 (3.35 to 14.32)[b]	6.85 (3.37 to 10.33)[b]	2.07 (−1.91 to 6.06)
Cohen's *d* effect size T0-T2	1.47	1.42	0.31
(95% CI)	(−0.95 to 3.88)	(−0.35 to 3.17)	(−2.16 to 2.78)

Note: T0: baseline, T1: 1 week after intervention, T2: 4-week follow-up. Clinical cut-off point ADAMS Depression subscale = 14. Clinical cut-off point SDL-ID total score = 35.

[a]Mean score below clinical cut-off point.

[b]Significant difference (a significant level of $p = .017$ (0.05/3) was used to correct for increased risk of a type 1 error due to multiple comparisons).

professional caregivers of those in both BLT groups were asked to complete a questionnaire about the expectations of the BLT intervention. Besides, the professional caregivers were asked to report compliance, adverse events and side effects in a daily log during the intervention. In case of a serious adverse event (SAE), such as hospitalizations, serious illness or death, professional caregivers were asked to report to the researchers immediately. We retrieved information on sex, age, level of intellectual disabilities, use of medication, residential setting, treatment during study intervention and BLT in the past by participants' medical and psychological files.

2.5 | Statistical analyses

Data were analysed using IBM SPSS Statistics 24. Prior to the start of the study, we stated in our study protocol that the intention-to-treat basis shall be used. None of the participants assigned to one of the three study groups switched to another study arm. Missing data on T1 and T2 were not imputed but reported. Baseline characteristics of the participants, baseline depression scores and baseline ABC Irritability scores were checked for any significant differences between the three groups. Expectations prior to the BLT, total amount of BLT days, compliance with the intervention

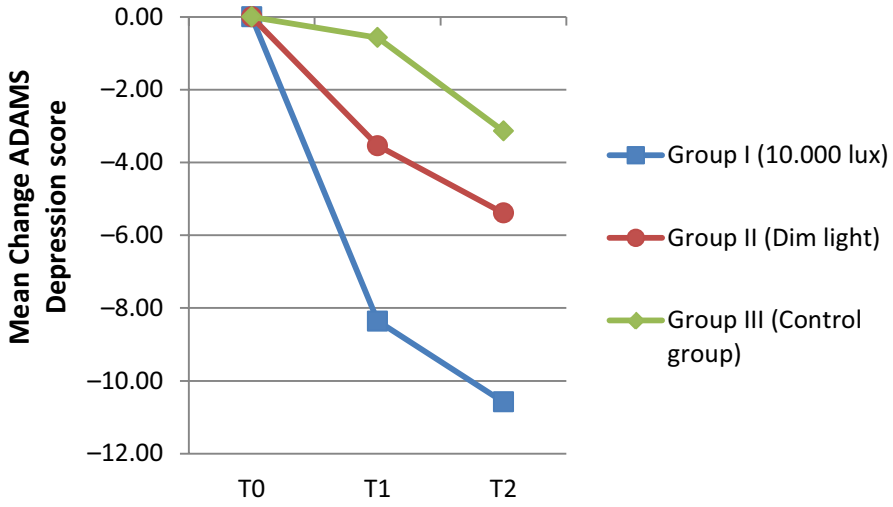

FIGURE 2 Mean change in ADAMS Depression subscale score (13 items) in patients randomly assigned to one of the three study groups [Colour figure can be viewed at wileyonlinelibrary.com]

and date of the intervention/control group period (quarter) were analysed with one-way ANOVA (2-sided) for continuous data and chi-squared tests for categorical data to check for confounders. Baseline differences between the groups were taken as a confounder into the analyses.

To investigate the effect of BLT on depressive symptoms, multivariate regression analyses were used. The ADAMS Depressive Mood subscale of group I and group II was compared separately with those of group III (control group). Independent-samples *t* tests were used to investigate whether there was a significant difference in effect of BLT between both intervention groups. Repeated-measures ANOVA was used to investigate the effect of BLT at follow-up (4 weeks after the end of BLT). For the subgroup analyses, paired-samples *t* tests were used to investigate the ADAMS Depression subscale scores on T1 and T2 in the three different study groups. A Bonferroni correction resulted in a significant level of $p = .017$ (0.05/3). A Bonferroni correction corrects for increased risk of a type 1 error due to multiple comparisons. Effect sizes were measured using Cohen's *d*. All statistical analyses mentioned above were also conducted with the SDL-ID total scores.

3 | RESULTS

3.1 | Patient characteristics

Between May 2015 and September 2017, 41 participants were included in our trial. Twelve participants were randomly assigned to group I, 15 participants to group II and 14 participants to group III. Figure 1 shows the flow diagram of our study. One participant of group II was excluded after the intervention, because there was no compliance to the study protocol (14 days of BLT were given in a 6-week period, instead of in a 2-week period). The characteristics of the participants of the three groups are presented in Table 1. The participants were aged between 24 and 81 years, and all levels of intellectual disabilities were covered in this study. According to norms of Zeilinger, Weber, and Haveman (2011), 60.0% of our total sample had an ABC Irritability percentile ranking score above 80% (Zeilinger et al., 2011), which means these participants had a considerable amount of challenging behaviour.

On baseline, there were significant differences in "sex" between the three groups ($p = .024$) and we corrected for this baseline difference as appropriate. Expectations prior to the BLT ($p = .056$), total amount of BLT days ($p = .060$), compliance with the intervention ($p = .420$) and date of the intervention/control group period (quarter of the year) ($p = .058$) were checked for the possibility of influencing the T1 depression scores. None of these variables were confounders. At baseline, none of the participants was classified with a major depressive disorder. There were no significant differences between the three groups on baseline ADAMS depressive symptoms ($p = .390$) and SDL-ID total score ($p = .709$).

3.2 | Primary outcomes

Table 2 shows the clinical outcomes on depressive symptoms measured on baseline (T0), 1 week after the intervention (T1) and 4 weeks after the end of the intervention (T2). The multivariate regression analyses showed no significant differences between groups I and III on depressive symptoms measured with the ADAMS Depression subscale on T1 ($p = .199$) and no significant differences between group II and group III on T1 ($p = .451$).

3.3 | Secondary outcomes

Independent-samples *t* test revealed no significant differences between group I T1 and group II T1 ADAMS Depression subscale scores ($p = .394$). Likewise, there were no significant differences between group I T1 and group II T1 SDL-ID scores ($p = .101$). Repeated-measures ANOVA was used to examine whether the effect of BLT was still visible 4 weeks after the end of BLT. We used the ADAMS Depression subscale scores at time 1 (baseline, T0), time 2 (1 week after BLT, T1) and time 3 (4-week follow-up, T2). In group I, Mauchly's

TABLE 3 Participant characteristics (n = 36)

	Group I BLT 10,000 lux n = 11	Group II BLT dim light n = 11	Group III Control group n = 14	p-value[a]
Sex				
Male (%)	4 (36.4)	3 (27.3)	11 (78.6)	**.022**
Female (%)	7 (63.6)	8 (72.7)	3 (21.4)	
Age, years				
Mean (*SD*)	57.64 (10.61)	58.82 (9.72)	52.07 (14.29)	.408
Level of intellectual disabilities (%)				
Mild	5 (45.5)	1 (9.1)	2 (14.3)	**.026**
Moderate	2 (18.2)	1 (9.1)	8 (57.1)	
Severe	3 (27.3)	7 (63.6)	2 (14.3)	
Profound	1 (9.1)	2 (18.2)	2 (14.3)	
Medication use (%)[b]				
Antidepressants	6 (54.5)	5 (45.5)	6 (42.9)	.763
Antipsychotics	8 (72.7)	6 (54.5)	8 (57.1)	.657
Benzodiazepines	4 (36.4)	5 (45.5)	3 (21.4)	.565
Anti-epileptics	4 (36.4)	3 (27.3)	2 (14.3)	.558
Contraception	2 (18.2)	1 (9.1)	1 (7.1)	.670
Beta-blockers	1 (9.1)	0 (0.0)	1 (7.1)	.621
Anxiolytics	0 (0.0)	0 (0.0)	0 (0.0)	.446
Melatonin	0 (0.0)	1 (9.1)	0 (0.0)	.420
No medication used	1 (9.1)	3 (27.3)	2 (14.3)	.516
Missing data	0 (0.0)	0 (0.0)	1 (7.1)	
ABC Irritability subscale				
Mean (*SD*)	8.64 (4.30)	12.00 (7.64)	12.00 (6.45)	.473
Total BLT days				
Mean (*SD*)	13.36 (0.92)	13.09 (0.94)	*n*.a.	.501
Date of BLT intervention/control group period, *n* (%)				
1st Quarter of the year	6 (54.5)	2 (18.2)	6 (42.9)	**.026**
2nd Quarter of the year	4 (36.4)	3 (27.3)	4 (28.6)	
3rd Quarter of the year	0 (0.0)	0 (0.0)	3 (21.4)	
4th Quarter of the year	1 (9.1)	6 (54.5)	1 (7.1)	

Abbreviations: ABC, the Aberrant Behavior Checklist; BLT, bright light therapy; ID, intellectual disability; *n*.a., not applicable; *SD*, standard deviation.

[a]Calculated as comparisons of the three groups, using ANOVA for continuous variables or chi-square tests for discrete variables. The comparison of total BLT days was only calculated for the two intervention groups.

[b]Some participants used more than 1 medication. Significant test values are in bold type.

test, $\chi^2(2) = 4.70$, $p = .095$, did not indicate any violation of sphericity. There was a significant effect for time in this group ($p = .008$). Post hoc tests using the Bonferroni correction for multiple comparisons revealed significant differences on ADAMS Depression subscale scores between time 1 and time 3 in group I ($p = .004$). In group II, Mauchly's test, $\chi^2(2) = 1.72$, $p = .423$, did not indicate any violation of sphericity and there was a significant effect for time as well ($p = .013$). Post hoc tests using the Bonferroni correction showed significant differences between time 1 and time 3 ($p = .008$) in this group.

The results of the subgroup analyses (paired-samples t tests) including the effect sizes measured with Cohen's d can be found in Table 2. In group I, we found a significant difference with a very large effect size ($d = 1.52$) between T0 and T1 ADAMS Depression subscale scores ($p = .003$). We also found a significant difference with a very large effect size ($d = 1.75$) between T0 and T2 ADAMS Depression subscale scores in group I ($p = .001$). In group II, a significant difference with a medium effect size ($d = 0.73$) was found between T0 and T1 ADAMS Depression subscale scores ($p = .015$). Furthermore, we found a significant difference with a large effect size ($d = 0.87$) between T0 and T2 ADAMS Depression subscale scores ($p = .004$). In group III, no significant differences were found between T0 and T1 ADAMS Depression subscale scores ($p = .787$). Likewise, we found no

TABLE 4 Outcomes ADAMS Depression subscale and SDL-ID (n = 36)

	Group I 10,000 lux	Group II BLT dim light	Group III Control group
ADAMS Depression subscale T0			
Mean (*SD*)	22.36 (5.43)	19.36 (3.64)	19.43 (4.70)
ADAMS Depression subscale T1			
Mean (*SD*)	13.60 (5.97)[a]	15.45 (7.44)	18.86 (7.38)
ADAMS Depression subscale Change T0-T1			
Mean (95% CI)	9.10 (3.96 to 14.24)[b]	3.91 (0.84 to 6.98)	0.57 (−3.91 to 5.05)
Cohen's *d* effect size T0-T1	1.62	0.70	0.10
(95% CI)	(−0.70 to 3.93)	(−1.63 to 3.03)	(−2.11 to 2.30)
ADAMS Depression subscale T2			
Mean (*SD*)	11.91 (6.98)[a]	14.10 (8.08)	16.29 (8.42)
ADAMS Depression subscale Change T0-T2			
Mean (95% CI)	10.46 (4.95 to 15.96)[b]	5.70 (1.57 to 9.83)[b]	3.14 (−1.62 to 7.91)
Cohen's *d* effect size T0-T2	1.75	0.88	0.48
(95% CI)	(−0.74 to 4.24)	(−1.62 to 3.38)	(−1.96 to 2.91)
SDL-ID total scores T0			
Mean (*SD*)	38.55 (6.82)	39.36 (3.70)	37.57 (6.16)
SDL-ID total scores T1			
Mean (*SD*)	30.90 (5.56)[a]	35.73 (6.53)	38.07 (7.98)
SDL-ID total scores Change T0-T1			
Mean (95% CI)	8.40 (3.37 to 13.43)[b]	3.64 (−1.11 to 8.38)	−0.50 (−4.24 to 3.24)
Cohen's *d* effect size T0-T1	1.20	0.72	−0.07
(95% CI)	(−1.52 to 3.93)	(−1.40 to 2.83)	(−2.62 to 2.47)
SDL-ID total scores T2			
Mean (*SD*)	30.00 (5.75)[a]	33.10 (6.19)[a]	35.50 (7.62)
SDL-ID total scores Change T0-T2			
Mean (95% CI)	8.55 (2.50 to 14.59)[b]	6.60 (2.07 to 11.13)[b]	2.07 (−1.91 to 6.06)
Cohen's *d* effect size T0-T2	1.42	1.31	0.31
(95% CI)	(−1.09 to 3.93)	(−0.74 to 3.36)	(−2.16 to 2.78)

Note: T0: baseline, T1: 1 week after intervention, T2: 4-week follow-up. Clinical cut-off point ADAMS Depression subscale = 14. Clinical cut-off point SDL-ID total score = 35.

[a]Mean score below clinical cut-off point.

[b]Significant difference (a significant level of p = .017 (0.05/3) was used to correct for increased risk of a type 1 error due to multiple comparisons).

significant differences between T0 and T2 ADAMS Depression subscale scores (p = .178). Table 2 also shows the subgroup analyses with paired-samples t tests of the SDL-ID scores and the effect sizes measured with Cohen's d.

Figure 2 shows the mean change in ADAMS Depression subscale scores over time in the three groups. In group I, the mean ADAMS Depression subscale score and the mean SDL-ID score on T1 and T2 decreased below the clinical cut-off points. In group II, only the mean SDL-ID score on T2 was below the clinical cut-off point. In group III, no mean scores on T1 and T2 decreased below the clinical cut-off points.

In group I, 75.0% of the participants had a decreased ADAMS Depression subscale score on T1. In group II and group III, this was 71.4% and 57.1%, respectively. When further examined, the depression scores of 45.5% of the participants in group I and 7.7% of the participants in group II were decreased 40% or more after BLT. In group III, 14.3% of the participants had 40% or more decreased depression scores after their control group period.

The multivariate regression analyses with the SDL-ID scores on T1 showed significant differences between group I and group III (p = .046). It was found that "group" significantly predicted the T1

SDL-ID scores (p = .014). There were no significant differences on T1 SDL-ID scores between group II and group III (p = .401).

After the analyses for the whole sample (n = 40), we checked whether BLT with <10 days (in a period of 14 days) influenced the outcomes. Therefore, we repeated all analyses in a sample excluding the participants who had <10 BLT days in the 14-day period. In total, one participants of group I and three participants of group II were excluded for these sample analyses (n = 36). The patient characteristics of this sample can be found in Table 3, and depression outcomes of this sample can be found in Table 4. In this sample, we did not find significant differences between the BLT groups and control group or between both BLT groups on our primary outcome measure.

3.4 | Adverse events and side effects

No serious adverse events or adverse events were reported during this trial. A minimum amount of side effects were registered in the daily logs. Headache was reported twice in group II, and fatigue or drowsiness was mentioned three times in group I and once in group II. In the daily logs, other striking behaviour regarding the BLT was reported as well: some participants turned away their face or body from the lightbox. In group I, this was reported four times and in group II six times.

4 | DISCUSSION

Non-pharmacological treatment options for adults with intellectual disabilities and depressive symptoms are limited. As far as we know, this is the first multicentre randomized controlled trial investigating the effect of BLT on depressive symptoms in adults with intellectual disabilities. We found no significant effect between the three trial groups on our primary outcome. However, the results of our secondary analyses suggest that BLT with 10,000 lux decreases depressive symptoms directly after the intervention period and at follow-up, showing very large effect sizes. In the dim light group, there are also significant decreases in depressive symptoms directly after the intervention and at follow-up with medium to large effect sizes. We did not find significant decrease of depressive symptoms in our control group.

Prior to the current study, only a couple of case reports (Altabet et al., 2002; Cooke & Thompson, 1998; Tsiouris, 2007) and one feasibility study (Hermans et al., 2017) were published on BLT for adults with intellectual disabilities and depressive symptoms. Positive results were found in these first explorations of BLT to decrease depressive symptoms in adults with intellectual disabilities, but these must be interpreted with caution because of the lack of a randomization procedure and control groups. Therefore, the strengths of the current study, for example the block randomization and blinding procedures, and the strictly protocolled intervention, make this study adding important information to the existing literature (Hamers, Festen, et al., 2018). As most studies, our study has a couple of limitations which must be mentioned. The first limitation is the small sample size of the three groups. During our study, we faced a number of obstacles (Hamers et al., 2017). From the 120 potential participants who were signed up for the study, only 41 could be included in our trial. The strict inclusion criteria of our trial, for example the exclusion of people with bipolar disorder and people who use specific photosensitizing medications, contributed to the safety of our trial, but also lowered the number of participants enrolled in our study. With our small sample size, significant differences between the intervention groups and the control group, and between both intervention groups may be hard to find, due to a lack of power. The confidence intervals of the mean change between baseline and T1 and between baseline and T2 in group I suggest that in a larger sample, it is likely that significant differences could be found. The second limitation of our study is the high prevalence of psychotropic medication used in all three groups. Consequently, the BLT intervention in this study cannot completely be seen as a monotherapy, but more as an add-on treatment. Since it is known that in the population of adults with intellectual disabilities (and depressive symptoms), high numbers of psychotropic medication are used, our sample seems quite representative.

It is interesting to note that in our study, antipsychotics are used more frequently than antidepressants, which was quite unexpected because exclusion criteria of our study prevented including participants with psychotic symptoms or bipolar disorder. Furthermore, in our sample, antipsychotics are used more often than in samples of adults with intellectual disabilities without depressive symptoms. From existing literature, we know that a large part of adults with intellectual disabilities use antipsychotics off-label for challenging behaviour (de Kuijper et al., 2010). It is possible that in our study, a large part of the participants who use antipsychotics have depressive symptoms which are being expressed with challenging behaviour (also regarding the high scores on the ABC Irritability subscale at baseline), and therefore treated with off-label antipsychotics. Further, negative symptoms caused by antipsychotic medications, such as apathy, the incapability to show emotions or social withdrawal, can be rated by the caregivers as depressive symptoms, and hereby increase the depression score.

Except for a significant difference in depressive symptoms between group I and group III after the intervention measured with one questionnaire in our secondary outcomes, we did not find any significant differences in depressive symptoms between the 10,000 lux condition, dim light condition and care as usual. However, we did find that half of the participants recovered for at least 40% from their depressive symptoms after 10,000 lux BLT and <15% recovered for at least 40% after dim light BLT or no-BLT (control group). Overall, we do see a positive trend in decreasing depressive symptoms in our 10,000 lux BLT group, with the number of depressive symptoms even beneath the clinical cut-off points after the intervention. This makes BLT a promising intervention to decrease depressive symptoms in

clinical practice. Therefore, RCTs with larger sample sizes (also with and without used psychotropic medication) are needed to further investigate the (direct) effect of BLT on depressive symptoms of adults with intellectual disabilities.

In summary, to the best of our knowledge, this is the first multicentre RCT investigating the effect of BLT on depressive symptoms in adults with intellectual disabilities. Our results show significant decreases of depressive symptoms in both intervention groups, but not in the control group. Overall, significant differences between both intervention groups, and between the intervention groups and control group were not found, which is possibly due to a sample size problem. Trial replications with larger samples are needed. Compared to psychotropic medication, BLT has limited side effects, is not expensive and can have immediate effect after a short period. This makes BLT a promising non-pharmacological treatment option to decrease depressive symptoms in adults with intellectual disabilities.

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CONFLICT OF INTEREST

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DATA AVAILABILITY STATEMENT

Requests for sharing the anonymous database of this trial should be addressed to the corresponding author.

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