



A multicenter randomized controlled trial for bright light therapy in adults with intellectual disabilities and depression: Study protocol and obstacle management



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ABSTRACT

Due to the limited cognitive and communicative abilities of adults with intellectual disabilities (ID), current treatment options for depression are often limited to lifestyle changes and pharmacological treatment. Bright light therapy (BLT) is an effective intervention for both seasonal and non-seasonal depression in the general population. BLT is an inexpensive, easy to carry out intervention with minimal side effects. However, knowledge on its anti-depressant effect in adults with ID is lacking. Obstacles in realizing a controlled intervention study in this particular study population may have contributed to this lack. To study the effect of BLT on depression in this population, it is necessary to successfully execute a multicenter randomized controlled trial (RCT). Therefore, the study protocol and the management of anticipated obstacles regarding this trial are presented.

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1. Introduction

Depression can be difficult to recognize and diagnose in people with intellectual disabilities (ID) because of their cognitive and verbal limitations and different manifestations of depression in this group compared to the general population (Hurley, 2008; Marston, Perry, & Roy, 1997). For example: crying, expressions of irritability, withdrawal and challenging behavior are common characteristics in adults with ID and depression (Charlot, Silka, Hurley, Lowry, & Pary, 2007; Hurley, 2008; Moss et al., 2000), but not part of standard diagnostic criteria (American Psychiatric Association, 2013). As a result, depression is poorly recognized in adults with ID (Hermans, Beekman, & Evenhuis, 2013). Nevertheless, depression is a common psychiatric disorder among adults with ID (Cooper, Smiley, Morrison, Williamson, & Allan, 2007; Hermans et al., 2013), which can lead to social, cognitive and physical problems and has a negative impact on their quality of life (Alonso et al., 2004; Beekman et al., 2002; Bijl & Ravelli, 2000; Coryell et al., 1993; Hays, Wells, Sherbourne, Rogers, & Spritzer, 1995; Judd et al., 2008; Murray & Lopez, 1997; Sprangers et al., 2000). However, there are barely any treatment options besides pharmacological treatment, especially for adults with severe or profound ID. In the Netherlands, cognitive behavioral therapy is one of the most regular therapies for depression, besides medication. Cognitive behavioral therapy can only be used in a small proportion of adults

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with ID due to their intellectual and verbal impairments. As a result, the current treatment options for adults with ID and depression are often limited to lifestyle changes (such as increasing activities) and pharmacological treatment. Because there is a high prevalence of polypharmacy in adults with ID (Haider, Ansari, Vaughan, Matters, & Emerson, 2014), the use of (an extra) medication is not preferred. Besides, the known side effects of anti-depressants are also inconvenient and, unfortunately, it can take some time for the anti-depressants work sufficiently.

Several studies indicate that depression is associated with disturbances in the circadian rhythms (Boyce & Barriball, 2010; Bunney & Potkin, 2008; Germain & Kupfer, 2008; McClung, 2007; Monteleone, Martiadis, & Maj, 2011; Wirz-Justice, 2006). Circadian rhythms (for example: sleep-wake cycle, hormone levels and body temperature) are primarily controlled and regulated endogenously by several biological clocks which are located at different places in the body (Hastings, Maywood, & Reddy, 2008). The main biological clock is located in the hypothalamus brain region in the suprachiasmatic nucleus (SCN). Light is the major Zeitgeber of this main biological clock and influences the circadian rhythms via retinal light input (Wirz-Justice, 2006) if there is no eye disease (Reme, Rol, Grothmann, Kaase, & Terman, 1996). Other external factors, such as (social) activities, mealtimes, work schedules and rules and habits of a care institution, can influence these circadian rhythms as well (Boivin & Boudreau, 2014; Kazemi et al., 2016; Naylor et al., 2000).

It is known that light exposure influences the level of the hormone melatonin in a healthy brain (Griefahn, Kuenemund, & Robens, 2006). When the amount of light decreases, the production of the hormone melatonin, which is created by the pineal gland and which influences feelings of sleepiness, increases by input of the SCN. Melatonin itself has also influence on the melatonin receptors in the SCN (Arendt, 2006; Stehle, von Gall, & Korf, 2003; Wirz-Justice, 2013). Thus, the release of melatonin follows a circadian rhythm and changes in this release may occur due to a disrupted circadian sleep-wake rhythm. It is known, that many adults with depression experience tiredness and sleeping difficulties like insomnia (Almeida & Pfaff, 2005; Kaneita et al., 2006; Murphy & Peterson, 2015) and older people with ID have a significantly less stable and more fragmented sleep-wake rhythm than the general population (Maaskant, van de Wouw, van Wijck, Evenhuis, & Ehteld, 2013).

The hormone cortisol is released during stress and the level of cortisol is associated with depression (Dettenborn et al., 2012; Hardeveld et al., 2014; Vreeburg et al., 2009). A chronically elevated cortisol secretion is associated with psychological and physical health problems such as high blood pressure, diabetes mellitus and depression (Schoorlemmer, Peeters, van Schoor, & Lips, 2009; Vreeburg et al., 2009). Treatment of depression may lead to a decrease in stress, which can lead to a decrease of the level of cortisol.

In the general population, Bright Light Therapy (BLT) is an effective intervention for both seasonal and non-seasonal depression and has been studied widely since the 1980s (Even, Schroder, Friedman, & Rouillon, 2008; Golden et al., 2005; Kripke, 1998; Lieverse et al., 2011; Morgan & Jorm, 2008; Pail et al., 2011; Rosenthal et al., 1984; Schwartz & Olds, 2015; Thaler et al., 2011; Tuunainen, Kripke, & Endo, 2004; Wirz-Justice, 2013). Golden and colleagues showed in their review and meta-analyses that the effects of BLT are comparable to those of anti-depressants (Golden et al., 2005). However, in a recent systematic review, Mårtensson and colleagues argued that the evidence of the effectiveness of BLT is inconclusive, partially because of methodological shortcomings of several studies (Mårtensson, Pettersson, Berglund, & Ekselius, 2015). Nevertheless, the overall experience with BLT for treatment of depression is positive. Another advantage of BLT is that it hardly causes side-effects as opposed to pharmacological treatment of depression. Besides, it will also reduce the costs of depression-treatment because BLT is relatively inexpensive and seems easy to deploy.

Although BLT has been studied since a couple of decades in the general population, only a few case reports have been published on its effect in adults with ID (Altabet, Neumann, & Watson-Johnston, 2002; Cooke & Thompson, 1998; Tsiouris, 2007). The results of these case reports seem promising, as BLT decreased the number of depressive symptoms.

A pilot study into feasibility of BLT and using actigraphy in adults with ID was recently conducted (Hermans et al., 2016, submitted). Fourteen participants (eight men, average age 52) with moderate to profound ID were included. Hermans and colleagues concluded that caregivers indicated that BLT and the use of actigraphy was feasible for all participants. Also the severity of depressive symptoms had been decreased, but the results should be interpreted with caution because of the small sample size and the lack of a control group.

As BLT seems to influence the biological clock in the brain, it may have a different effect on depression in adults with ID, due to impaired brain development or brain damage. Consequently, research outcomes of BLT studies in the general population cannot be generalized to adults with ID. Furthermore, also environmental variables, for example time spent outside in daylight, may differ from the general population and can interfere with the effect of BLT in adults with ID. As a consequence, it is unclear whether BLT has the same anti-depressant effect in adults with ID as in the general population.

Although it is of great importance to investigate non-pharmacological treatment for depression in adults with ID it is quite understandable that so far, no high-quality effect studies have been performed. Indeed, apart from meeting general requirements for randomized controlled trials (RCT) (sample size with adequate power, representativeness, randomization, blinding, adequate statistics, budget), research in populations with ID generally has to meet specific challenges. Each study requires its own scenario with a detailed identification of potential obstacles, solutions, responsibilities and time slots. In this paper, we will describe the study protocol and how we have managed the anticipated obstacles.

2. Methods

2.1. Objectives

The primary objective of this study is to investigate the effect of BLT on depressive symptoms in both intervention groups compared to regular care (control group). Our secondary objectives are: investigating if there is a significant difference in

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