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Parental Adherence to a Research Protocol to Investigate the Effect of the Wilbarger Therapressure Program™: A Qualitative Study

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Parental Adherence to a Research Protocol to Investigate the Effect of the Wilbarger Therapressure Program™: A Qualitative Study

Abstract

Background: The Wilbarger Therapressure Program™ is a technique applied by parents at home for sensory overresponsivity in children. The program is anecdotally reported to be demanding on parents, which can affect parental adherence. Currently, there is an absence of high quality research to support the use of the program. This pilot study aimed at developing appropriate research protocols to investigate the effectiveness of the program on the stress response of children with sensory overresponsivity. This article reports on the second phase of the project.

Method: After participating in the trial data collection protocols to investigate the effect of the intervention, five participants participated in semi-structured interviews that sought to obtain their perceptions on the data collection protocols and explore their adherence to the protocols.

Results: The participants acknowledged the demanding nature of involvement in the study; however, participant adherence was high. The participants were motivated to be involved and to contribute to the intervention outcomes and the research. The participants described the aspects that influenced their adherence.

Conclusion: The participants provided suggestions for future, larger studies.

Keywords

Pilot Study, Adherence, Parents, Wilbarger, Therapressure Program™, sensory, qualitative

Cover Page Footnote

The authors wish to thank Dino Mennillo for his support with recruitment and his expertise with the Wilbarger Protocol. We also thank the families for their participation.

Credentials Display and Country

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Background and Literature Review

Parental involvement in occupational therapy, by way of home programs for their children, is common and is seen as an effective and efficient way of delivering health services. Novak, Cusick, and Lannin (2009) concluded that the use of occupational therapy home programs leads to observable gains in function and quality of movement. It is recommended that therapy should focus on the expectations of parents (Cohn, Kramer, Schub, & May-Benson, 2014) and that family-focused intervention, with collaborative goal setting, will result in improved outcomes for families (Brewer, Pollock, & Wright, 2014). Foster, Dunn, and Lawson (2013) and Graham, Rodger, and Ziviani (2009) mutually advocate for a parent coaching intervention model instead of direct child-focused intervention. Indirect health service delivery models, like home programs, are typically recommended when the therapist determines that increased repetition, in addition to or in lieu of direct intervention, could benefit the child's therapeutic outcomes (Bundy, Lane, Murray, & Fischer, 2002).

Nonadherence by parents to direct and indirect health interventions for their children, however, is a serious and common issue. DiMatteo (2004) reported on a meta-analysis of 569 studies that showed nonadherence rates averaging at 25% across treatments. A study by Moore and Symons (2009) of 235 parents of children with autism and developmental disorders found that adherence was as high as 84% for medications but only 76% for behavioral treatments. Moreover, recent estimates for adherence to physiotherapy home programs is as low as 54% (Chappell & Williams, 2002), while

engagement in multidisciplinary treatments for chronic pain can be as low as 47% (Simons, Logan, Chastain, & Cerullo, 2010).

The reasons for abandoning health interventions are complex, but they can include a lack of support, equipment, social support and relationships; health beliefs; and perceived efficacy of the treatment (Moore & Symons, 2009). Peplow and Carpenter (2010), in a qualitative study of four parents who administered home programs to their children with Cerebral Palsy, found that the programs were focused on the child's impairment and needed to be integrated into the home routines and family practices. According to these authors, families also needed to be given a clear role in evaluating the outcomes. Segal and Beyer (2006), in their systematic review of the impact of home programs on families, found that there are concrete and conceptual issues that influence the integration of home treatment programs into the daily lives of families. Among these concrete issues were competing demands and a lack of time, support, and skill, all of which hinder the integration of home treatment programs into family life. It seems clear that the integration of home treatment programs into the daily lives of families is complex but important if the family is to adhere. Other authors have argued that focusing on improving the parents' adherence to therapeutic home programs will improve the children's adherence. Springer and Reddy (2010) found that measuring parental adherence to a program for managing behavior in children with Attention Deficit and Hyperactivity Disorder improved the adherence and therapeutic outcomes, and King, Berg, Butner, Butler, and Wiebe (2014) found a

direct correlation between the adherence of parents to a diabetes management regimen and the adherence of the children.

The Wilbarger protocol (2014) is an intervention that is commonly implemented by parents as a therapeutic home program (indirect service) to address sensory overresponsivity in their children. Segal and Beyer (2006) studied adherence to the Wilbarger protocol and found a number of causes for nonadherence. They include the children's reactions to the interventions, the parents' perceived efficacy of the intervention, and issues with daily schedules. Moreover, Bhojti and Brown (2013), in their study of five families who administered the Wilbarger protocol, recommended that parental experience be studied, as they perceived an excessive toll on the parents.

This paper reports on the experiences and adherence of parents to a research protocol. The quantitative results are reported in a previous paper (Weeks, Boshoff, Stewart, Shona, & Della Vedova, 2016) in which researchers evaluated the feasibility of parents administering a research data collection protocol while concurrently implementing the Wilbarger intervention protocol to their children in home and natural environments. The data collection protocol asked parents to collect salivary cortisol and heart rate variability (HRV) measurements from their children at three time points per day during baseline and follow-up phases, and at one time point every second day during the intervention phase. The intervention phase was the Therapressure Program™, which was administered every 90 to 120 min on consecutive days for 2 weeks. The parents had already incorporated a sensory diet into their children's

routine prior to the commencement of the study.

The parents showed high adherence (100%) to the collection of salivary cortisol and HRV data in the baseline phase of the study; however, the adherence lagged to 80% for both measures during the intervention phase when the impact of administering both protocols was the highest. This had a carryover effect into the follow-up phase where adherence was 80% and 70%, respectively, whereby parents felt they could have better adhered if they did not have to collect data during the intervention phase.

The importance of understanding the experience of the parents and their adherence to home-based interventions was made clear from previous reports in the literature. In our study, we were adding the burden of a data collection protocol to an already onerous and complex treatment program, so we were interested in how the parents managed the combination of the procedures.

The aim of this qualitative study was to explore how the parents who participated in the quantitative pilot study experienced the added demands of the physiological data collection protocol in addition to implementing the Wilbarger intervention protocol. Our research questions were:

- What are the perceptions of the parents involved in the pilot study regarding the feasibility of data gathering while concurrently conducting the Wilbarger protocol with their children?
- What recommendations can the parents make to improve adherence and efficiency

of conducting both the Wilbarger protocol and the pilot data collection procedures?

Method

Research Design

A descriptive qualitative research design using semi-structured interviews was used, as this was an exploratory study (DePoy & Gitlin, 2005). Ethics approval for the study was gained from the Human Research Ethics Committee of the university, and the research has been performed in accordance with the ethical standards laid down by the 1964 Declaration of Helsinki and its later amendments.

Participant Selection and Recruitment

The participants in this study were drawn from the pool of parent participants in the preceding quantitative Wilbarger protocol pilot research study (Weeks et al., 2016). Five of the six parents who participated in the pilot study agreed to participate in the interviews. The sixth parent had moved interstate and was unable to be contacted. All of the parents involved in the study signed consent forms and agreed to the audio recording of their interviews.

Research Instruments and Data Collection

Semi-structured interviews were used to collect in-depth data on focused topics pertinent to the research question (Minichiello, Aroni, Timewell, & Alexander 1995). The interviews consisted of questions designed to elicit critical reflection of the parents' experiences of the Wilbarger protocol and accompanying data collection procedures. After spending time to build rapport with the participants, the researchers asked open-ended questions inviting in-depth discussion and included aspects that worked well

and those that did not work well for each of the data collection protocols. The parents were asked to make recommendations for a future, larger scale study. The parents were given the opportunity at the end of the interview to reflect on the information provided and to add any missing information. The interviews ranged from 30 to 45 min each. The first interview served as the pilot interview to determine the suitability of the questions. Three interviews were conducted by one researcher and two by another—both experienced qualitative researchers. The researchers (the first and second authors) followed the same interview protocol for all of the interviews. The investigator triangulation was used where more than one researcher conducted interviews and were involved in the data analysis for confirmation purposes (Thurmond, 2001). The researchers were not known to the parents, had no existing relationship with them, and had no involvement with the parents during the quantitative pilot research study. The Therapressure ProgramTM and data collection calendar (Appendix A), an example of a daily data collection protocol for baseline and follow-up phases (Appendix B), and an example of a daily data collection protocol for the intervention phase (Appendix C), have been provided to illustrate the procedure about which the parents were interviewed.

Data Analysis

Verbatim transcripts of the interviews were read by the first and second authors and analyzed thematically using a framework analysis approach (Ritchie & Spencer, 1994; Ritchie & Lewis, 2003). This involved reading all of the transcripts in full in order to familiarize the

researchers with the data, developing themes based on close analysis of the transcript, and developing a thematic framework. Indexing and charting then occurred of all the data into the thematic framework. This then allowed for further refinement and associations to be developed. All of the transcripts were read by two researchers, both of whom conducted independent analyses of the data before developing a consolidated analysis.

Participant Demographics

As mentioned, five of the six parents who participated in the pilot study were available to be interviewed. All of the participants were Australian mothers who were married and between 25 to 40 years of age. The participants ranged from having moderate to high levels of access to economic resources when assessing their postcodes against Socio-Economic Indexes for Areas (SEIFA) scores (Australian Bureau of Statistics, 2008). All of the participants were accessing the services of a private occupational therapist. The parents ranged in the number of children they had, from one to three: three of the parents had two children, one had one child, and another one had three children.

Findings

A number of themes were found that are presented under two domains: “Wilbarger protocol” and “Data collection”. The second theme included subthemes reflecting each of the measurement protocols: salivary cortisol, HRV, and use of the sensory profile questionnaire (Dunn, 1999).

Theme 1: Wilbarger Protocol: It is Hard Work but Worth It

An important theme that arose from the responses was that the parents went in with their eyes open, expecting it to be hard work. One parent commented, “I knew that it was going to be intense, and I was mentally prepared for it.” They found that it was hard work to make it a part of their routine, but that they were able to, and were mostly able to adapt their lives to it. The parents found that the practical management of the Wilbarger protocol was hard, for example, managing the brushing in public places, in cold weather, or when visiting family. Many made significant changes to their social schedules so they could focus on the protocol. A parent mentioned that “it is work. It’s not something that just easily slips into the day.” Another parent likened it to the rigours of breastfeeding when she felt under continual time pressure. A parent stated, “Always being aware of the time, always watching the clock. Always saying, where’s that brush?” This same parent found that she had so adapted to the protocol that “If you stand next to me, you will get brushed.” The responses indicated that the Wilbarger protocol was hard work and was disruptive of family life, but that it was worth doing.

The parents gave a number of suggestions for the protocol, including doing it during school holidays (preferably summer break to allow for clothes to be taken off), and not planning any outings while doing the protocol. When asked what she would say to a parent considering participating in a similar study, a parent said “it’s worth trying, definitely.”

Theme 2: Data Collection: Committed to Making it Work

The parents managed to collect data while implementing the Wilbarger protocol, and adherence to the data collection procedures was high. As with the Wilbarger protocol, parents were very positive toward the study and committed to make it work. A parent said, “Yeah, yeah, I mean I think on a personal level, I want to contribute because I think that for children who have sensory issues, I think there’s a whole lot more out there that we need to know about.” The children were also committed to the data collection. The parents reported that their children were motivated to provide the measurements and to be involved in “important science.” A parent illustrated her child’s commitment to the research project by stating, “Yeah, he wanted to be a part of this (project), and he was very excited to be a part of this (project), and he actually felt a little bit like he’d let down the research because he couldn’t spit” (referring to the cortisol data collection procedure).

There is no doubt that the data collection protocol (taking saliva samples and HRV measurements) added to the parents’ burden. Two parents reported that they would prefer not to take the measurements while implementing the intervention. A parent mentioned, “I was really getting to a point at the end where I was just exhausted and over it. Rob is an extremely patient child and he was really good the first week. He is really good like that—a placid child. I just looked at him—he had enough by the end, I have had enough.” Two parents needed further instructions about how to gather the data, but most of them

liked the clear recording schedule and that it was all kept in a folder (see Appendices A-C).

Subtheme 2A: Cortisol data collection: Let them play with it. Spitting in the small cup to produce a saliva specimen was hard for four of the children, but a number of strategies helped, including having a glass of water beforehand, allowing the child to play with the container, and letting the child find his or her own way of depositing the saliva, as well as rewarding the child by allowing him or her to see how much was produced. One child was not able to spit and found the idea so distasteful that the family discontinued this aspect of the data collection. A parent said, “I think the collection of the saliva was tricky in the beginning, but I just let Jenny play with the test tube, and eventually she worked out how to do it, and she was all excited and she measured how much.”

Subtheme 2B: Heart rate data collection: Interest in the heart beat ratings. The children were expected to wear an elastic chest strap containing a Polar heart rate transmitter for 15 min while they were lying still. Most of the parents allowed the child to watch a DVD or TV show in this time, and some of the parents found this particular task hard to fit into their lifestyle. It was surprising to find that the children were quite happy to wear the chest strap and that some were very interested in the results, watching their heart beat displayed on the Polar RS800CX™ watch. A parent said her child “was happy enough to wear the monitor, I didn’t think she’d like it because you have to wet it, and

she can't stand anything wet. But she was OK wearing it, so I was surprised."

Some parents did report being unsure of the degree of stillness their child needed to maintain during the 15 min data collection phase. A parent stated, "I don't think there was clarity about how still the child needs to be."

Subtheme 2C: Sensory profile: Refining timing and aspects covered. The parents completed the sensory profile twice. The parents completed the questionnaire easily, with one person commenting positively that she appreciated being able to reflect on changes in her child. Other parents questioned the ambiguous nature of the questions, the fact that small changes were not able to be acknowledged, and said they would have liked the capacity to comment on a range of other topics, notably sleep. Two parents would have preferred more time to have passed following the Wilbarger protocol, as they felt, first, that they needed more time to observe their children in different environments and second, that changes may have magnified with time.

Discussion

The parents reported that they were able to collect the physiological stress response data as well as administer the Wilbarger protocol, although they found it hard work. The surprising result was that the children were able to cope with a fairly intrusive data collection regimen of spitting to collect cortisol and remaining still for

15 min to collect HRV data while wearing the

heart rate sensor strap on their chests, as well as submitting to the Wilbarger brushing and joint compressions. While reported adherence was high, 2 weeks seemed to be a manageable amount of time, and the parents were quite willing to stop the procedures after this time.

The parents reported that the impact on their families of administering the Wilbarger protocol and gathering data was high. They reported that fitting both protocols into their usual daily routines was difficult but important in order to make it work. The strategy of fitting new routines into existing routines is supported by other researchers, such as Peplow and Carpenter (2010). The parents adjusted their routines and took on the onerous research data gathering because they were very motivated to improve their children's lives. The data collection added to their usual workload, although this seems to have been mitigated by the motivating effect reported by their children and themselves of feeling they were contributing to research and improving the lives of their own and other children. An important strategy used by the parents was that they allowed their children to feel involved, to understand why they were doing it, and to have fun by helping solve the problems posed by the data collection procedures.

Implications for Practice and Research

Insights have been gained on parent adherence to the implementation of the Wilbarger protocol itself, which is useful for therapists when considering recommending this protocol for parents to implement. The parents were involved in the decision to take part in the study and were committed to making it work. The parents

anticipated that the protocol would have outcomes for their children and they made significant efforts to adjust their family routines to implement it. In addition, features involved in adherence seem to be the child's willingness and ability to tolerate the procedures, supported in literature by Segal and Beyer (2006), and the parents' willingness to adapt their routines. The fact that the Therapressure Program™ and data collection protocols ran for 2 weeks was significant to the parents, as it corresponded with school holiday times and was a manageable amount of time for parents to make changes to routines. From the findings of this study, the following implications for practitioners considering asking parents to gather data while implementing the Wilbarger protocol are:

- Ensure parents and children understand the reason for the research and are well prepared for the laborious nature of it and how to fit it into their family routines.
- Ensure the children's engagement and interest in collecting saliva and heart rate data by including the children in the reasons for the data collection and allowing them to solve some of the administration problems. This strategy is supported by the literature provided by King et al. (2014), which illustrates the importance of giving attention to adherence by both the parents and the children.
- Give consideration to the time period during which the protocols (data-collection and Wilbarger) are administered. From this study, the parents have recommended

summer and holiday periods. The summer holiday period is longer, which may be more appropriate to schedule intervention when the Therapressure Program™ is individualized and prescribed for longer than 2 weeks.

Limitations and Future Research

The qualitative interviews conducted as a follow up to the quantitative pilot study (Weeks et al., 2016) provided additional in-depth data from the participants' perspectives on the suitability of the data collection procedures used in the pilot study. The findings of this study relate specifically to the parents who participated in the pilot study and are specific to parents who have illustrated their commitment to following the Wilbarger protocol and data collection procedures. The participants were Australian mothers from middle to high socio-economic status, who were accessing private services, employed, married, and varied in terms of having other children. Findings may not be transferable to other population groups.

Conclusion

In this study, the parents' views were obtained on their involvement in a pilot study that involved implementation of the Wilbarger protocol simultaneously with collecting physiological data from their children. The parents reported that it was time consuming and hard. They managed, however, to adhere to the protocols due to a number of factors, including commitment to the reason for the research, the ability to fit the protocols into daily routines, their children's ability to cope with the procedures, their children's interest and engagement in the

data collection, and the fact that they had clear information and instructions from the start. A number of suggestions were made for future research of a similar nature. In addition, these insights and implications apply when addressing parent adherence to the Wilbarger protocol itself.

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Appendix A

Calendar Overview of Intervention and Data Collection Protocols

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
24/6/12 Complete 'Sensory Profile Questionnaire' by Fri 29 th June 2012	25	26	27	28	29 School ends - Term 1	30 BASELINE DAY 1 (Collections #1, 2 & 3)
1/7/12 BASELINE DAY 2 (Collections 4, 5 & 6)	2 THERAPRESSURE DAY 1 (Collection # 7)	3 THERAPRESSURE DAY 2	4 THERAPRESSURE DAY 3 (Collection # 8)	5 THERAPRESSURE DAY 4	6 THERAPRESSURE DAY 5 (Collection # 9)	7 THERAPRESSURE DAY 6
8 THERAPRESSURE DAY 7 (Collection # 10)	9 THERAPRESSURE DAY 8	10 THERAPRESSURE DAY 9 (Collection # 11)	11 THERAPRESSURE DAY 10	12 THERAPRESSURE DAY 11 (Collection # 12)	13 THERAPRESSURE DAY 12	14 THERAPRESSURE DAY 13 (Collection # 13)
15 THERAPRESSURE Day 14 FINAL DAY	16 School returns - Term 2	17	18	19	20	21
22	23	24	25	26	27	28 FOLLOW-UP DAY 1 (Collections 14, 15 & 16)
29 FOLLOW-UP DAY 2 (Collections 17, 18 & 19)	30	31 Complete second 'Sensory Profile Questionnaire' before Sun 4 th Aug 2012	1/8/12	2	3	4

Appendix B

Example of a Daily Data Collection Protocol for Baseline and Follow-up Phases

DATA COLLECTION RECORD SHEET – completed by the parent

BASELINE: DAY 1

Collection #1

Day 1:

Date: _____ (MORNING
SAMPLE)

Child wakes up

Estimated time child wakes _____ a.m.

Water to drink

Heart rate measurement

15mins recorded on the watch? Yes No

Was my child lying on his/her back? Yes No

Did the child move while lying down? Yes No

If Yes, please describe

Saliva sample

Saliva collected in container #1 Yes No

Estimated time of collection _____ a.m.

Sample taken 30-45mins after child wakes Yes No

Comments

Day 1: _____ **Date:** _____ (JUST BEFORE LUNCH)

Water to drink

Heart rate measurement

15mins recorded on the watch? Yes No

Was my child lying on his/her back? Yes No

Did the child move while lying down? Yes No

If Yes, please describe

Saliva sample

Saliva collected in container #2 Yes No

Estimated time of collection _____a.m/p.m.

My child has had water only in the last 30mins

Yes No

Comments

Day 1: _____

Date: _____

(JUST BEFORE BED)

Water to drink

Heart rate measurement

15mins recorded on the watch? Yes No

Was my child lying on his/her back? Yes No

Did the child move while lying down? Yes No

If Yes, please describe

Saliva sample

Saliva collected in container #3 Yes No

Estimated time of collection _____p.m.

My child has had water only in the last 30mins

Yes No

Comments

Appendix C

Example of a Daily Data Collection Protocol for the Intervention Phase

DATA COLLECTION RECORD SHEET – completed by the parent

During the Therapressure Program™

Collection #7

Day 1: _____ **Date:** _____ (MORNING)

Child wakes up Estimated time child wakes _____ a.m.

Water to drink

Heart rate measurement 15mins recorded on the watch? Yes No

Was my child lying on his/her back? Yes No

Did the child move while lying down? Yes No

If Yes, please describe _____

Saliva sample Saliva collected in container #7 Yes No

(30mins after child wakes) Estimated time of collection _____ a.m.

Sample taken 30-45mins after child wakes Yes No

Comments _____

Therapressure Perform one application as instructed by your OT

Heart rate measurement

15mins recorded on the watch? Yes No

Was my child lying on his/her back? Yes No

Did the child move while lying down? Yes No

If Yes, please describe _____

Continue the Therapressure Program™ for the rest of the day as instructed by your OT – no further data collection required for the day.