

# Using a Repeated-Measures Design in Pediatric Oncology Studies

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## **Discipline**

Medicine [D23]

## **Sub-discipline**

Pediatric Medicine [SD-MD-21]

## **Academic Level**

Intermediate Undergraduate

## **Contributor Biography**

**Dr. Marie Vander Haegen** is currently a researcher and lecturer at the University of Liège and at the Haute Ecole Léonard de Vinci (university graduates) in Belgium. She earned her PhD in 2017. Her scientific work is on psychological and cognitive adjustment among parents of a childhood cancer survivor. Her doctoral thesis was related to the concept of intolerance of uncertainty and its influence on parental adjustment (psychological, cognitive, somatization). During her doctoral work, she developed and used new models for understanding the parental experience of having a child who has survived cancer. She focused in particular on the relationship between the intolerance of uncertainty and its consequences on cognitive processes and clinical distress. In 2017, Marie Vander Haegen accepted a scientific collaborator position at the University of Liège, where she has worked since that time. Since 2019, she has served as a scientific collaborator at the University of

Paris Descartes (France) where she is developing a project related to e-Health and parents of a childhood cancer survivor and childhood cancer patient. Her current research looks at the development of e-Health and new technologies in the field of pediatric chronic diseases (cancer, cystic fibrosis, diabetes).

### **Published Articles**

Vander Haegen, M., Stassart, C., Tilkin, C., Grégoire, C., & Flahault, C. (2019). *Collection Psychologie du social: Ajustement psychoclinique de l'adulte et de l'enfant dans le champ de l'oncologie: Perspective du patient et du proche* [Psycho-clinical adjustment among adults and children in the field of oncology: Patient and caregiver perspective]. Éditions des archives contemporaines.

Vander Haegen, M., & Stassart, C. (2018). De l'expertise scientifique à l'expertise profane [From scientific expertise to profane expertise]. In M. Préau & A. Siméone (Eds.), *Collection Psychologie du social: Ajustement et régulation en contexte pédiatrique* [Adjustment and regulation in a pediatric context] (pp. 105–111). Éditions des archives contemporaines.

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## **Abstract**

In the field of pediatric oncology, I noticed a lack of repeated-measures designs in pediatric oncology assessing the relationship between specific personality risk factors and parental adjustment. Prior studies had utilized mainly cross-sectional designs (studies that analyze data at a specific point in time), and few of them had examined the role of personality in psychological adjustment among parents of a childhood cancer survivor. This case study provides an overview of my experience conducting a quantitative study using a repeated-measures design with parents of a childhood cancer survivor. In this case study, I outline methodological strengths and challenges of this type of study. I also highlight some recommendations for conducting quantitative studies with parents of a childhood cancer survivor.

## **Learning Outcomes**

By the end of this case, students should be able to

- Understand the process of using a repeated-measures design in psycho-oncological studies
- Analyze advantages and disadvantages of using a repeated-measures design

- Identify challenges to recruiting parents of a childhood cancer survivor into studies

## Case Study

### Project Overview and Context

Cancer remains a rare disease during childhood, and the prognosis for childhood cancer has dramatically improved. Compared with the total cancer burden in Belgium and Western countries, childhood cancer accounts for less than 1% of total cancer cases. Every year, about 320 children (<15 years) and 180 adolescents (15–19 years) are diagnosed with cancer in Belgium (55% boys and 45% girls). Four prime treatments (chemotherapy or cytotoxic treatments, radiation therapy, surgery, and bone marrow transplantation) are available for pediatric cancers, all of which are aimed at eradication and overthrow (Belgian Cancer Registry, 2019).

In my professional experience with parents of a childhood cancer patient or survivor, I have observed severe parental distress when the child is diagnosed in remission. Many families are surprised by anxious feelings and lingering worry related to late effects of treatment that arise during this long-awaited time, because they expected to feel only relief. So, the remission time is considered a time of continued adjustment for parents.

In 2014, I had the opportunity to prepare a doctoral thesis (PhD) in the field of pediatric oncology at the University of Liège (Belgium). I began my research with an exhaustive literature review to target key findings, concepts, and developments related to parental adjustment in pediatric oncology. The literature review revealed that the majority of studies used a cross-sectional design and were focused mainly on parents of a childhood cancer patient (Vander Haegen & Luminet, 2015). Cross-sectional studies had highlighted positive outcomes for parents, such as new positive life perspectives, family closeness, and togetherness during the child's remission. In addition, some protective factors for parental adjustment had been observed such as social support or marital cohesion during that time. For

instance, a high level of perceived social support was related to a high perceived sense of mastery and low perceived stress and led to less distress in parents of a childhood cancer survivor.

Sometimes, though, late effects of treatment (e.g., musculoskeletal or cardiopulmonary impairment) or physical problems related to childhood cancer can lead to intense distressing emotions for the parent that need medical attention and vigilance (Bowers et al., 2013; Brinkman et al., 2013). The great majority of cross-sectional studies observed intense symptoms among parents, such as posttraumatic stress symptoms (PTSS), anxiety, depression, sleep disturbances, fear of recurrence, and lingering worries, but also a trend toward “somatization,” which refers to the conversion of mental states to physical symptoms such as sleep disorders or gastric problems (e.g., Bruce et al., 2011). Moreover, the literature identified several risk factors such as female gender, prior trauma, low level of social support, parental history of depression or anxiety, and personality risk factors such as pessimism or anxiety-trait leading to distress among parents and poor adjustment (e.g., Brinkman et al., 2013; Bruce et al., 2011).

Depending on the research focus, interest in risk factors that predict parents’ adaptation has been very selective in the literature. A risk factor can be defined as a characteristic (e.g., biological, psychological, family) that is associated with more negative outcomes for the individual. For instance, low self-esteem may lead to a mental disorder such as an episode of depression. However, prior to my study, no study had integrated the factor of “uncertainty” into pediatric oncology studies. Uncertainty is a natural and normal phenomenon, which is inherently related to the medical context (e.g., relapse, side effects of treatment). So, parents have to deal with and adjust to a normal uncertain context.

To understand the life situation of parents and propose effective support for them, I thought it was important to investigate factors associated with uncertainty, as well as its

consequences for parents' long-term psychological effects. Therefore, I decided to explore the concept of uncertainty, and I conducted a second literature review (Vander Haegen & Etienne, 2016). My objectives were to understand which factors could be related to uncertainty in health. By reading articles, I discovered the concept called "the intolerance of uncertainty" (IU). All prior studies had observed IU as a risk factor. IU is defined as a stable personality trait whereby an individual has negative beliefs about uncertainty and uses several dysfunctional strategies to control the uncertainty (e.g., positive beliefs about worry, cognitive avoidance, rumination, and negative problem orientation).

IU has been associated with various anxiety disorders (Birrell et al., 2011; Carleton, 2016; Reuman et al., 2015). In addition, studies revealed that IU's intensity does not change over time (e.g., Boswell et al., 2013; Nestadt et al., 2010). Therefore, my research study aimed to identify how parents of a childhood cancer survivor deal with uncertainty using the Intolerance of Uncertainty Scale (IUS) model (Dugas et al., 1998).

The IUS model attributes a key role to IU and additional roles to dysfunctional strategies (e.g., cognitive avoidance, positive beliefs about worry) in the development and maintenance of worry, the core feature of generalized anxiety disorder (GAD). GAD is a type of anxiety disorder characterized by uncontrolled worry, feeling on edge, and impaired social or occupational functioning.

Because the IU factor does not change over time, I decided to conduct a quantitative study with a repeated-measures design to obtain more definitive information about the stability of IU over time. In the study, parents filled in several questionnaires; these questionnaires were specifically created by the authors who developed the IUS model (Dugas et al., 1998) and have good to excellent reliability for diagnoses of anxiety disorders.

In this case study, I will discuss my experience conducting a quantitative study using a repeated-measures design and highlight its advantages and disadvantages. I will also

comment on what I did to mitigate these challenges and offer some suggestions that can be utilized in other projects.

#### **Section Summary**

- Studies in pediatric oncology have used mainly cross-sectional designs.
- Prior studies on parents of a childhood cancer survivor had not included “uncertainty” as a risk factor, so I decided to fill this gap in the literature.

## **Research Design**

The decision to use a quantitative study was guided by my research objectives. The first was to quantify IU’s intensity; the second was to compare IU’s intensity over time. I hypothesized that parents who were identified as intolerant of uncertainty at the first assessment would preserve this trait at the second assessment, because it is a relatively permanent personality trait. The third was to examine the role of associated difficulties with respect to IU (e.g., cognitive avoidance, negative problem orientation) over time. I hypothesized that parents who were intolerant of uncertainty would also exhibit these associated difficulties related to IU at both assessments.

In addition, studies had highlighted (Carleton, 2016) that IU is not easy to detect with a qualitative study (e.g., through interviews). Concerning IU’s stability, I ruled out a cross-sectional study, because it would not have been relevant for my objectives. Cross-sectional studies cannot show stability over time as they analyze data from a single point in time. So, I decided to use the repeated-measures design with two assessments to observe whether IU’s intensity could change over time. Simultaneously, I needed to decide on the amount of time that would lapse between the two assessments. In the field of health, studies using this design retest participants either at 3, 6, 9, or 12 months later (Oberfeld & Francke, 2013). Because parents return to the hospital only one time per year when their child is in remission, and because IU’s intensity seemed as if it might be stable over time, I chose to retest parents only

twice and fairly early. So, I conducted the retest 3 months after the first assessment, with the same parents and the same questionnaires (two assessments).

### **Questionnaires Related to the IUS Model**

1. *The IUS*. (Freeston et al., 1994). The IUS is a 27-item self-report instrument that assesses beliefs about uncertainty.
2. *The Why Worry Questionnaire Second Version (WW-II)* (Gosselin et al., 2003). The WW-II is a 25-item self-report measure containing five subscales of which each subscale assesses one type of positive belief about worry: problem solving, motivation, emotion, magical thought, and positive personality trait.
3. *The Negative Problem Orientation Questionnaire (NPOQ)* (Gosselin et al., 2005). The NPOQ is a 12-item self-report instrument that assesses dysfunctional cognitive patterns influencing the ability to solve daily life problems.
4. *The Cognitive Avoidance Questionnaire (CAQ)* (Gosselin et al., 2002). The CAQ is a 25-item measure of the tendency to use cognitive avoidance. CAQ contains five subscales, each of which assesses one type of avoidance strategy: substitution, transformation, distraction, avoidance, and thought suppression.
5. *The Mini Cambridge–Exeter Repetitive Thought Scale (Mini-CERTS)* (Douilliez et al., 2014). The Mini-CERTS is a 14-item scale assessing seven constructive (i.e., CET; “concrete experiential thinking”) and seven unconstructive (i.e., AAT; “abstract analytical thinking”) modes of thinking.

### **Questionnaires Related to Clinical Distress**

1. *The Hospital Anxiety Depression Scale (HADS)* (Zigmond & Snaith, 1983). The HADS is a 14-item instrument assessing anxiety (seven items) and depression (seven items).



2. *The Psycho Soma-Oncology Scale (PSOS)* (Vander Haegen & Etienne, 2015a) is an eight-item self-report instrument that assesses psychosomatic symptoms. The PSOS examines six dimensions: insomnia, loss of energy, weight, gastrointestinal symptoms, headaches, and sexual disorders.

*The Penn State Worry Questionnaire (PSWQ)* (Meyer et al., 1990). This scale is a 16-item self-report instrument that assesses excessive and pathological worry, and items are rated on a 5-point Likert-type scale. **The PSWQ examines the worry frequency and intensity in general without focusing to a specific topic and the general instruction into the PSWQ is to choose the response that best describes how the individual dealt with the worry in their life. For my specific topic (i.e., parents of a childhood cancer survivor), I retained 10 of the 16 PSWQ items that were relevant to parents. The instruction was modified and presented as follows:**

“about the evolution of my child’s health.” Examples of the items include “My worries overwhelm me” (Item 1) (QIPS-R15) (Vander Haegen & Etienne, 2015b).

All the questionnaires were rated on a Likert-type scale.

#### **Section Summary**

- This was a quantitative study using a repeated-measures design with a retest 3 months after the first assessment.
- I based the study on the IUS model.

## **Research Practicalities**

The study took place in two centers treating childhood cancer in Liège, Belgium. The study started in 2015 (September) and ended in **2016** (May). I conducted follow-up telephone calls and sent letters to make plans for data collection. Parents were eligible for the study if they were French-speaking, if their child had been diagnosed in remission for 4 to 6 years (without relapse), and if the child had received neoadjuvant chemotherapy (a chemotherapy

that is administered before radiation therapy and/or surgery). Parents were excluded if they were not French-speaking, if their child had been diagnosed in remission less than 4 years prior or more than 6 years prior to the study, and if the child had undergone only surgery or only radiation therapy (without neoadjuvant chemotherapy).

I specifically took parents of a child who had been treated first by chemotherapy, because this treatment leads to more side effects in the long run (e.g., dental problems, heart problems) and thus this care environment naturally increases parental worries. In addition, I wanted to observe parental adjustment around the fifth year of the child's remission (gold standard in pediatric oncology). Therefore, I focused my research on parents of a child who had survived cancer between 4 and 6 years prior, and I created three groups of parents: (1) parents of a child cancer survivor in remission for 4 years (Group 1), for 5 years (Group 2), and for 6 years (Group 3).

I tested these three groups of parents twice: at treatment completion (either 4, 5, or 6 years) (Time 1) and 3 months later. Parents responded to eight questionnaires at the first assessment (Time 1). Five questionnaires were related to the IUS model, and I added three questionnaires to identify their level of clinical distress. Three months later, parents returned to the laboratory and completed the same questionnaires again (second assessment/Time 2).

## **Ethical Considerations**

I decided to recruit parents from two medical institutions (multicenter study) to have a good sample size for future statistical analyses. The sample size was calculated before the study began using the "G\*Power" statistical software, which indicated a sample of at least 50 parents was needed to produce a robust statistical study.

Hospital ethics committees are two independent structures whose role includes giving an opinion on all protocols for experimentation on humans prior to implementation. So, I transmitted to both hospital ethics committees a protocol including several documents (e.g.,

detailed summary, informed consent, declaration of insurance form, questionnaires). I also presented my research protocol to the hospital ethics committees. After a review process (e.g., measure of risk, ethics), the hospital ethics committees accepted the research plan, the study received an identification code, and the study could begin.

During the follow-up telephone calls, parents were often highly motivated to support my research that may improve outcomes for future patients and parents. Some form of parental altruism can play a role in deciding to participate in research, but only when parents have a firm conviction that the research will benefit future patients and parents. The main risks were that parents' anxiety would be exacerbated through their participation in my study and that topics probed in questionnaires could make parents uncomfortable. My research team, composed of my doctoral supervisor and researchers at the University of Liège with extensive experience in managing the parent group, supported me in conducting the study. The team helped me brainstorm and develop new ideas for statistical analyses.

### **Planning and Juggling Data**

I allocated eligible parents into three groups, which meant that I needed to plan and to coordinate a long list of patients. This meant contacting the coordinating nurse in each center (two hospitals) to obtain the patient list, selecting eligible parents, and obtaining their personal information with the agreement of the department head. In 2015, regular meetings with both coordinating nurses were necessary to update the listing. Simultaneously, I created three tables to effectively track all parents. The first table showed medical information retrieved from medical databases (e.g., type of cancer, remission time). The second concerned questionnaire data, and the third was a summary table involving the interpretation of all the questionnaires. I inspected data three times and checked for any errors (e.g., inputting errors).

<b>Section Summary</b>
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- The role of the ethics committee is both necessary and obligatory in studies on parents of a childhood cancer survivor.
- I needed to track all parents and coordinate a long list of patients.

## **Method in Action**

One challenge I encountered was recruiting sufficient parents to have a good sample size for statistical analyses. I overcame this difficulty by recruiting participants from two hospitals, rather than one. There were 61 parents at the first assessment (45 mothers and 16 fathers), which was a sufficient sample size.

The next challenge I encountered was a loss of participants. Unfortunately, 10 parents were unable to perform the second assessment 3 months later. Three of the 10 could not complete the second one because of an inability to attend the assessment (e.g., moving, on holiday), and seven of the 10, because they were at work (51 of 61 parents: 39 mothers and 12 fathers). The biggest drawback in a repeated-measures design is known as “the attrition phenomenon,” which refers to missing data over time (participants drop out).

I dealt with this challenge by explaining to the parent at the first assessment that there would be a retest, by selecting a large sample size, and by choosing a short period of time between the assessments. Through these strategies, I was able to reduce the attrition phenomenon. Parents knew that a retest would occur, which made them less likely to drop out before the retest. The large sample size made it possible for the study to continue even though some participants did drop out between the two assessments. The short period of time that passed between the assessments made it less likely that changed circumstances would become an obstacle to participation.

Another challenge I faced was that the parents were not easy to reach, because their children visited the hospital for a check-up just once a year. Fortunately, by collaborating

actively with the medical teams of the two hospitals, I was able to get in touch with parents because coordinating nurses regularly gave me information, such as check-up dates.

#### **Section Summary**

- The attrition phenomenon is common in a repeated-measures design.
- Collaboration with a medical team facilitated contact with the parents in this study.

## **Practical Lessons Learned**

In hindsight, I should have planned the date of the retest with the parent at the first assessment to further reduce dropouts. In addition, I learned that two assessments are not sufficient to measure IU stability over time. I should have conducted three or four assessments. However, I still would have needed to consider the risk that parents may drop out at any point, and the chances that the study would have become less robust statistically would have increased with each additional assessment.

Over the course of my study, I observed advantages and disadvantages of using a repeated-measures design. One advantage was increased statistical power because this design can use fewer participants to detect an effect size (i.e., difference between the assessments). Another advantage relates to cost. This type of design is cheap to use. Disadvantages are that this type of study takes longer than other types and that parents may drop out before the second assessment.

I learned from this study that building strong relationships with referring health care professionals and a research team can bolster clinic-based recruitment efforts and the success of a project. Before contacting parents, I met with medical teams several times to explain the study and its goals extensively. These meetings promoted a trusting relationship and enabled active collaboration to plan the study (e.g., contacting the coordinating nurse first and working with her on data monitoring).

I met with my medical team and research team several times to ease their concerns about the study by reassuring them that the study would not create stress or anxiety for parents. Through these meetings in which I presented the study, its objectives, and the procedure (e.g., sample, questionnaires), I learned that taking time to build trusting relationships with a medical team is fundamental to successfully starting collaborations or projects with pediatric oncology teams.

#### **Section Summary**

- Advantages of the repeated-measures design include lower cost and increased statistical power with a smaller number of participants compared with other methods.
- Some disadvantages of the repeated-measures design are that it takes longer to complete a study of this type, and the drop-out rate is higher than that of other methods.

## **Conclusion**

Research methods in pediatric oncology are quite varied, as is the number of situations and settings. Because I was dissatisfied with the limitations of prior studies in pediatric oncology, I developed an alternative design strategy. I chose to use a quantitative study with a repeated-measures design. Through this design, I was able to gain insight into parental adjustment when a child had survived cancer and to identify some risk factors leading to lingering distress for the parent. I encountered challenges, including the recruitment and participation of medical teams in the study, and the specific challenges of using a repeated-measures design. Statistical analysis and techniques that I learned over the course of this study can be applied to many studies or projects in the field of pediatric oncology. I recommend the repeated-measures design for researchers who are interested in analyzing changes in data over time and who want to maximize the statistical power of their study despite a relatively small sample size.

### Section Summary

- Some challenges I encountered over the course of this study include recruiting participants and building medical teams willing to facilitate the study.
- A repeated-measures design is useful for studies of changes in data over time and studies that have a relatively small number of participants.

### Classroom Discussion Questions

1. What are some benefits of building a strong relationship with medical teams in pediatric oncology?
2. What are some disadvantages of conducting a repeated-measures design?
3. What strategies can decrease the attrition phenomenon?

### Multiple Choice Quiz Questions

The attrition phenomenon refers to:

- a. an instrumental bias related to the choice of questionnaires
- b. the loss of participants that occurs over the course of a research project
- c. a positive change from the participant that occurs during the course of a study

**Correct answer: b**

A repeated-measures design refers to:

- a. taking measurements on two groups at the same time
- b. taking measurements on one group at a time
- c. taking measurements on the same participants over time

**Correct answer: c**

One advantage of using a repeated-measures design is

- a. more statistical power with fewer participants
- b. less statistical power with fewer participants
- c. more statistical power with a lot of participants

Correct answer: a

## Declaration of Conflicting Interests

The Authors declare that there is no conflict of interest.

## Further Reading

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