

# The Development of an Early Intervention for Supporting Families of Persons With Acquired Brain Injuries: The SAFIR<sup>®</sup> Intervention

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## Abstract

Families of persons with acquired brain injuries need to be supported from the early phase of hospitalization. To date, no known early family intervention is available for this population. Using the Medical Research Council Framework, we developed a new intervention based on the Calgary Assessment and Intervention Models that includes the family preferences, clinician's expertise, and the contextual resources. This paper aims to describe the complete development process including a scoping review, an assessment of families and clinicians' needs, an evaluation of the contextual resources, and an adaptation of the theoretical framework. Using a systemic perspective, we tailored the new intervention to involve the stakeholder's preferences. The result is an early family intervention named SAFIR<sup>®</sup>, led by a clinical nurse specialist, including five core components and structured around three phases and a follow-up. The next steps will be focused on assessment of the clinical feasibility of this new intervention.

## Keywords

brain injury, family intervention, acute care, Family Systems Nursing

Acquired brain injuries (ABI) are a major health issue with significant global impact and long-term consequences to the person, the family, and the health care systems. ABI is a generic term that refers to all traumatic and non-traumatic brain injuries (TBIs) acquired after birth that are not related to a congenital or a degenerative disease, including any type of TBI or stroke. ABI are among the leading causes of adult impairment worldwide and are in the top five leading causes of death (Feigin et al., 2015; Heron, 2017). The incidence of ABI varies worldwide; in Europe, 2.5 million people suffered from a stroke or a TBI in 2010 (Gustavsson et al., 2011). The incidence of ABI is important: 69 million people suffer from a TBI each year around the world (Dewan et al., 2018) and one in four people worldwide will suffer a stroke in their lifetime (Timmis et al., 2018). ABI affects cognitive, physical, and emotional functioning of the person, including changes in mood, behavior, and personality (Capizzi et al., 2020), that can be overwhelming and difficult to deal with for both the patient and the family. The consequences of these changes on family functioning and family dynamics and well-being can result in families experiencing negative emotional responses such as anxiety, sadness, and anger.

Their family member with TBI is often physically present but psychologically absent (Boss, 2019; Karpa et al., 2020). Thus, each family member must cope and adopt to a new role of caregiver, which may result in additional burden. ABI caregivers have reported a significantly higher level of caregiver burden when compared to others (e.g., caregivers of advanced cancer or dementia patients) (Harding et al., 2015). This burden is likely to remain or increase overtime due to

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the often-permanent neurological damage of ABI. A recent study showed that time elapsed since the injury, level of dependency, and behavioral problems in people with ABI, are associated with lower levels of quality of life and positive perception of care, and higher levels of anxiety and depression in caregivers (Bermejo-Toro et al., 2020). Family involvement in inpatient rehabilitation programs has been found to have a positive impact on patient outcomes and community reintegration (Bogner et al., 2019). To support family functioning adjustment and promote mental health of family members by involving and considering families is thus highly recommended (Dharma, 2021; Moriarty et al., 2018; Rasmussen et al., 2020). This family support from health care professionals (HCPs) should be provided as early as possible, throughout the entire hospital stay, and beyond (Dawes et al., 2020; de Goumoëns et al., 2019; Kreutzer et al., 2015). This recommended practice has not yet been implemented and family support intervention to fill this gap is urgently needed.

In this context, nurses play a key role in family support and, in addition to having clinical neurosciences knowledge and skills, they must be competent in caring for the family (de Goumoëns et al., 2018, 2019; Rowat et al., 2016; Vaughn et al., 2016). This family support is particularly complex due to the evolving nature of the consequences of the injury on patients and families over time. Therefore, nurses in an advanced practice role should have the competencies required to meet the complex needs of these patients and their families, as well as to conceptualize, develop, and implement family nursing in complex situations (de Goumoëns et al., 2020; Vaughn et al., 2016). In other clinical contexts and population of patients, the role of advanced practice family nursing, based on Family Systems Nursing (FSN), has been shown to have the potential to meet the specific and complex needs of families in intensive care and to be of benefit to families and HCPs by facilitating interaction and communication (Naef et al., 2020).

FSN focuses on care that involves the entire family system (patient, family, and patient-family dyad) (Wright & Leahey, 2013). Nurses collaborate with families to create opportunities that reduce and alleviate emotional, physical, and spiritual suffering in the experience of illness (Wright, 2017; Wright & Bell, 2009). Family interventions have been shown to improve patient and family outcomes at both levels: the individual and the family as a whole (Chesla, 2010; Wright & Bell, 2009; Wright & Leahey, 2013). The positive effects of family interventions on the health of patients with a chronic illness and their family caregivers have been demonstrated (Chesla, 2010). Decreased readmission rates, emergency department visits, and family anxiety levels have also been demonstrated when testing family interventions in adults with a chronic condition (Deek et al., 2016). The findings from a scoping review reported that interventions for

TBI caregivers targeting family functioning and coping skills reduced family burden of care (Baker et al., 2017). A recent pilot study reported that a positive behavior support program for families of people with ABI in the community setting increase confidence in providing behavior support for their loved one (Fisher et al., 2021). Although there is an abundance of published articles on interventions to support patients with different types of diagnosis and their families, to the best of our knowledge, benefits of family interventions during the acute phase of hospitalization have not been reported in this ABI population (de Goumoëns et al., 2018).

Any family intervention by definition is complex, because it involves several aspects of behaviors, various outcomes, and requires flexibility and adjustability (Richards & Hallberg, 2015). A recent systematic review on family involvement for adults with a chronic disease recommended that greater attention to be paid to understanding contextual factors when developing and implementing family interventions (Gilliss et al., 2019). The development of such interventions requires a rigorous approach, the integration of a strong body of evidence, and a deep understanding of organizational and contextual factors (Craig et al., 2013; Gitlin, 2013; Melnyk, 2014). However, the literature illustrating the development and the implementation of family interventions in a real-life context is scarce. Researchers have, therefore, little evidence to refer to and face recurring pitfalls related to the process, the development, the monitoring, and the reporting of complex interventions. For the developed interventions to be transferred into practice and avoid research waste due to difficulties in interpreting published results and/or in replicating the intervention under study, international experts urge for more transparency and rigor in the reporting of complex interventions (Hoffmann et al., 2014; Walker et al., 2017). As only 14% of evidence is implemented into practice, Gitlin (2013) recommends spending more time on the preclinical phase. This recommendation is similar to the development of evidence-based practice guidelines: to develop the best care for patients and families, we need to focus on their characteristics, their needs regarding their particular conditions and their resources (Melnyk, 2014). Clinician expertise, resources of the institution or context, as well as research evidence, must be considered with the same attention. The Medical Research Council (MRC) Framework for Development and Evaluation of Complex Intervention in Health (hereafter, referred to as MRC Framework) was developed to guide researchers and clinicians in this process: we chose it as a methodological framework for the development of our new intervention reported here (Craig et al., 2013; Richards & Hallberg, 2015).

The aim of this research report is to describe the step-by-step process, using the MRC Framework, to develop a complex intervention for families of persons with ABI (called the SAFIR<sup>®</sup> intervention) in the acute phase of the injury.

## Methods

The MRC Framework for developing interventions is comprised of four phases (Craig et al., 2013). Phase 1 is the development, Phase 2 is the clinical feasibility assessment, Phase 3 is the implementation, and Phase 4 is the evaluation phase of the intervention. We followed Phase 1 of the MRC Framework to guide the development of the SAFIR<sup>®</sup> intervention. This phase included three steps: Step 1: Identify the evidence, Step 2: Identify or adapt a theory, Step 3: Model process and outcomes. Following the three steps of the MRC framework in Phase 1, we considered all essential elements during the pre-implementation and the development phases of the intervention, including stakeholders' involvement. This latter step ensured consideration of the stakeholders' expertise, preferences, and needs in the development and the delivery of the intervention. This is congruent with FSN, which calls for consideration of the family system, the health care system, and the environmental system.

Different modalities were used to achieve these three steps. Figure 1 presents the steps, the key elements, and the study designs related to each phase, as well as the usefulness of the results for the development of the intervention.

To comprehensively describe the intervention and ensure completeness of reporting, we used the Guidance for reporting for intervention development studies in health research (GUIDED) (Duncan et al., 2020), including the Template for Intervention Description and Replication (TIDier) checklist, available in supplemental material.

### Step 1: Identify the Evidence

Search for evidence was twofold and focused on: (a) family needs and (b) available interventions targeted toward families (families only or combined interventions for families and patients).

**Family needs.** We conducted an exploratory cross-sectional descriptive study to determine family's needs and satisfaction during the acute and rehabilitation phase of hospitalization in our local context, a neurosciences ward in a tertiary hospital, in Switzerland. The full report is presented elsewhere (de Goumoëns et al., 2019). The key elements of the method were as follows: the participants were the most significant family members identified by the ABI patient or his or her legal representative ( $n = 54$ ), the Family Needs Questionnaire (FNQ) (Kreutzer & Marwitz, 1989) was used, and the results were analyzed using descriptive statistics.

**Family-oriented interventions.** We conducted a systematic scoping review to examine the range and nature of family-oriented interventions that have been developed for and/or

tested in families of people with ABI in any health care setting. The full report is presented elsewhere (de Goumoëns et al., 2018). We described the characteristics of the intervention (type, provider, frequency, delivery mode, and duration) that were guided by FSN (Shajani & Snell, 2019; Wright & Leahey, 2013). We used the Joanna Briggs Institute Scoping Review method (Peters et al., 2015).

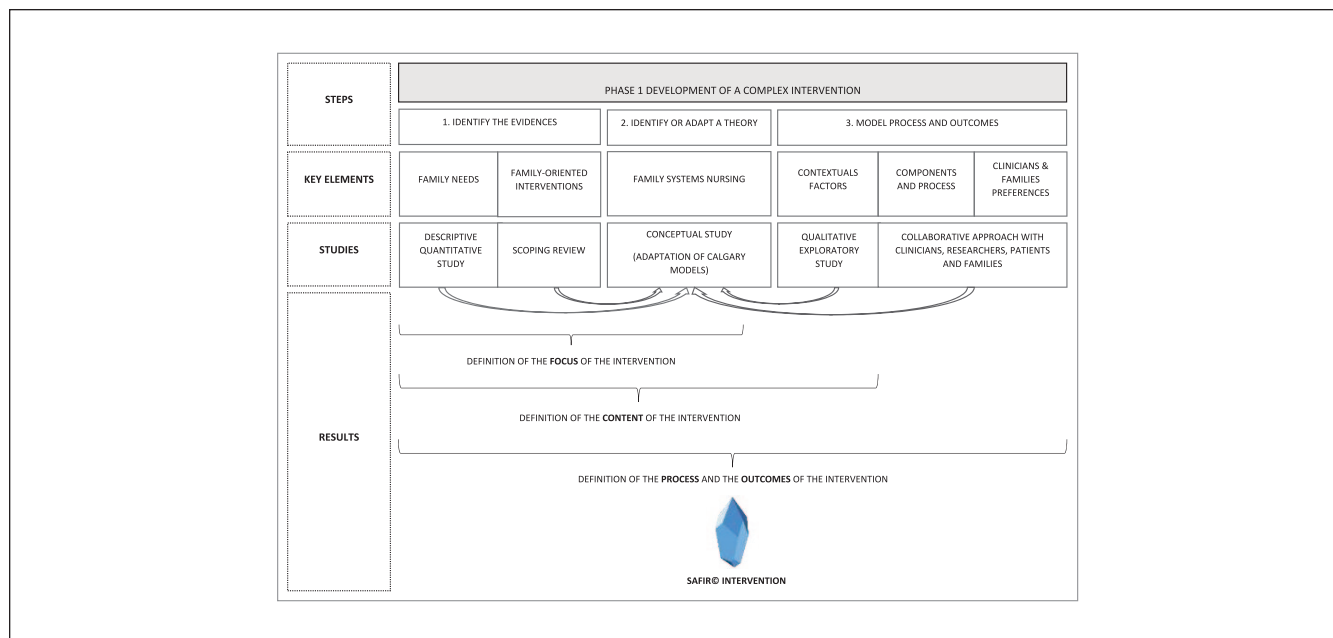
### Step 2: Identify or Adapt the Theory

The development of the SAFIR intervention required a theory that conceptualized the family as the unit of care, the relationship between the family and the nurse, and the reciprocity and the interaction between the family system and the health care system. For that reason, we used the Calgary Family Assessment Model (CFAM) and the Calgary Family Intervention Model (CFIM) (Shajani & Snell, 2019; Wright & Leahey, 2013), as these models allow the operationalization of these concepts. This choice was also justified as the models were already known and used in the institution. In the development of SAFIR<sup>®</sup>, the CFAM and CFIM provided the structure for the core components of the intervention itself as well as the key elements. We consulted the CFAM and CFIM theoretical foundations at every step of intervention development and adapted it to our unit, organizational context, and population.

### Step 3: Model the Intervention and the Outcomes

Modeling a complex intervention, such as SAFIR<sup>®</sup> before a full-scale evaluation is important to inform the design of both the components and process of the intervention with the involvement of clinicians and stakeholders (i.e., the families) (Craig et al., 2013). In Step 3, first we identified the potential pitfalls and resources with the aim of understanding the clinical context in which the intervention would be implemented, then we developed the core components, the process, and the handbook of our intervention integrating clinicians and family's preferences. The methods of each step are outlined below.

**Clinical contextual factors.** We conducted an analysis of the contextual factors that could influence the feasibility of our newly developed intervention, using an exploratory qualitative approach (Gray et al., 2017). The full report is presented elsewhere (de Goumoëns et al., 2020). We conducted eight semi-structured interviews, with nurses and allied health professional managers. The interview guide was developed based on the theory of FSN. The questions focused on the health professional managers' perception about family care for ABI patients hospitalized in their clinical settings. We analyzed our data with an inductive and deductive content analysis method (Mayring, 2004).



**Figure 1.** Study flow diagram of the SAFIR® intervention development.

*Integration of clinicians' and families' preferences.* Based on the results of these preliminary steps, we developed the core components, the process, and the handbook of our intervention: a preliminary version of SAFIR®. We submitted these documents to an expert panel composed of clinical experts for assessment using a Likert-type scale (not very important-moderately important-important-very important). The expert panel included seven clinicians with more than five years of experience in neurosciences and recognized as clinical managers and/or clinical leaders in the department.

## Results

### Step 1: Identify the Evidence

*Family needs.* Congruent with previous findings worldwide (Kreutzer et al., 2015; Norup et al., 2015), our results showed that families of patients suffering from ABI in Switzerland need regular consistent information and emotional support from all HCPs, yet these needs were not satisfied (de Goumoëns et al., 2019). Our work demonstrates room for improvement in these two domains and supported the need for a new intervention in this context.

*Family-oriented interventions.* Our systematic scoping review identified 64 different interventions. The 24 different core components of the recorded interventions can be classified in the three domains of the CFIM. The *cognitive domain* included 62% of the core components recorded in our review (education, coping skills strategies, information, problem-solving skills, psychoeducation, communication skills, prevention information, and advocacy competencies). The

*affective domain* included 24% of the core components (emotional and social support, multifamily group interventions, and relationship skills development). The *behavioral domain* included 4% of the core components (cognitive behavioral treatment, caregiver mediated exercises, and relaxation). We created a new domain, the *interprofessional domain*, that included 10% of the core components (coordination and continuity of care between family system and health care system, instrumental support, and health management). The two main core components that were the most frequent were education and emotional support.

The scoping review results informed the development of our intervention. First, we identified a gap in the timing of the intervention delivery. Out of the 64 interventions, only five (8%) were provided during the acute phase with the remainder during the chronic, transition, and rehabilitation phases of the illness. This element justified the development of a new intervention during the acute phase of hospitalization. Our results also showed that HCPs from various disciplines can provide care for families of patients with ABI, but the largest group of HCPs were nurses. These results highlighted the importance of developing a nurse-led intervention, integrating an interprofessional approach. Most interventions had irregular sessions (39%), lasted less than 3 months (47%), and were delivered in the form of face-to-face family meeting (52%). These elements allowed the emergence of a reflection on the frequency, the duration and the mode of intervention. These items were refined during the context analysis (Step 3).

The main outcomes measured out of the 64 interventions were mental health and burden. More than 50% of the interventions measured patient and family/caregiver outcomes,



informing on the relevance of considering the patient and the family as a unit of care. However, only four studies measured the family-functioning and three studies measured the coping strategies. Nevertheless, these outcomes appear to represent crucial elements when evaluating a family nursing intervention.

### *Step 2: Adaptation of the Theory*

Following the Phase 1, we adapted the theory by adding families' and clinician's preferences (evidence from the analysis of the contextual factors, see below) and the interprofessional domain (evidence from the scoping review). The addition to this latter domain was justified, because as illustrated in our scoping review, caring for ABI patients and families requires diverse competences from different health care disciplines. This dimension was, therefore, taken into consideration in the development of SAFIR<sup>®</sup> for a fully integrated intervention.

### *Step 3: Model the Intervention and the Outcomes*

**Contextual factors.** The results of our qualitative exploratory study showed four main categories (family system, health care system, collaboration, and care context) that are closely related to each other and fifteen sub-categories (de Goumoëns et al., 2020). The HCPs highlighted the importance of environmental factors (care context; architecture, location and moments of formal and informal meetings with families), as well as interpersonal factors (interdisciplinary collaboration and multidisciplinary collaboration). The characteristics and the interactions between the family and the health care systems were important. HCPs reported that current practice did not adequately or systematically consider families. The situations experienced by families and persons with ABI also appeared to have an impact on HCPs, who were calling for more structured family nursing care, including improvement in environmental factors, such as a designated meeting room. These latter factors should aim to facilitate meetings with families, improve interprofessional communication and collaboration, and provide continuous nursing education led by advanced practice nurses.

#### *Integration of clinicians and families preferences*

**Core components, aim and provider of SAFIR<sup>®</sup>.** The five core components of SAFIR<sup>®</sup> presented to the experts were as follows: (s) Family assessment, (b) Emotional support for the family, (c) Individualized information for family, (d) Family engagement in care, and (e) Interprofessional collaboration and care coordination. The seven experts rated all the five core components as very important. Then, we submitted these results to two family members living with a person suffering from ABI, from our National Brain Injury Association

(FRAGILE) to ensure that it was consistent with their needs. Therefore, all core components were retained at this step, providing a high flexibility in their modulation to be able to meet specific families' goals and priorities assessed during the family meetings. Based on the available evidence and the quality of nursing education (tertiary level), the expert panel advised that the provider of the intervention should be master-prepared clinical nurse specialists (CNS). In the context of this study, CNS followed a competency-based course in FSN using the advanced practice competencies for family nursing (Duhamel, 2015; International Family Nursing Association [IFNA], 2017; Wright & Bell, 2009; Wright & Leahey, 2013). In addition, we developed a specific handbook and study protocol training, integrating family meeting simulation for each SAFIR<sup>®</sup> provider.

The different sources of evidence, merged with the families and clinician's preferences, support the modeling of the content, the characteristics, and the process of our new intervention. Entitled SAFIR<sup>®</sup>, it is a nurse-led intervention that focuses on the relationship between the family members and the interprofessional health care team. SAFIR<sup>®</sup> aims to meet the individual needs of families early in the acute phase of their loved one's hospitalization. Table 1 presents the five core components of SAFIR<sup>®</sup>, their relation to the theoretical framework, the sub-components, the aim, the specific content, and the moment of delivery of each component.

**Intervention delivery process.** The intervention is structured to be delivered in three phases and a follow-up. Phase 1 aims to build a therapeutic relationship with the family of the persons suffering from ABI, Phase 2 aims to strengthen this relationship, and Phase 3 aims to prepare family for transition to the neurorehabilitation center. The follow-up aims to close the intervention process and the therapeutic relationship with the family.

Phases 1, 2, and 3 include three similar key moments: a briefing session with the CNS, the interprofessional team, and the researcher; a face-to-face family meeting with the CNS and the family; and a debriefing session with the CNS, the inter professional team, and the researcher who was a doctoral fellow focusing on family nursing. In the follow-up, the face-to-face family meeting was replaced by a telephone call to the family member by the CNS. Figure 2 shows the SAFIR<sup>®</sup> delivery process.

**Frequency, timing, and duration.** The frequency and the timing of our intervention was defined according to the body of evidence (de Goumoëns et al., 2018, 2019, 2020) and the expert panel. SAFIR<sup>®</sup> included four family meetings, during the first month of acute care hospitalization, in a dedicated office; the duration of each meeting ranged from between 15 and 60 min. It was designed for some flexibility in the delivery mode according to family preferences and availability as well as clinical resources availability.

**Table 1. SAFIR® intervention Core Components.**

SAFIR® Core component and relationship to theoretical framework	Sub-component	Aim	Content	Integration in SAFIR
<p><i>Family assessment</i> <i>Prerequisite to family intervention</i></p>	<p>Family assessment of</p> <ul style="list-style-type: none"> <li>• internal structure</li> <li>• external structure</li> <li>• family functioning</li> <li>• development phase</li> <li>• beliefs</li> <li>• priorities</li> <li>• major concerns</li> </ul>	<p>To have a deep understanding of the whole family situation in order to build a trusting relationship.</p>	<p>Genogram</p> <ul style="list-style-type: none"> <li>• Internal structure</li> <li>• Development</li> <li>• Family functioning</li> </ul> <p><i>Ecomap</i></p> <ul style="list-style-type: none"> <li>• External structure</li> <li>• Resources</li> </ul> <p><i>Circularity</i></p> <ul style="list-style-type: none"> <li>• Communication</li> <li>• Visiting organization</li> <li>• Routine</li> </ul> <p><i>Exploration of the Beliefs</i></p> <ul style="list-style-type: none"> <li>• Family level</li> <li>• Individual level</li> </ul>	<p>Phase 1-2-3 <i>Briefing</i> <i>Family Meeting</i> <i>Debriefing</i></p>
<p><i>Emotional support for the family</i> <i>Related to:</i> <i>Affective and cognitive domain</i></p>	<p>Emotional support from clinical nurse specialists using</p> <ul style="list-style-type: none"> <li>• Validate family feelings by active listening</li> <li>• Identify coping strategies related to their own strengths and beliefs</li> </ul>	<p>To understand the challenges, griefs, and fears that need to be addressed in order to be able to provide them with emotional support and to mobilize the family strength to overcome the issues during the acute phase of hospitalization.</p>	<ul style="list-style-type: none"> <li>• <i>Active listening</i></li> <li>• Talking about the situation</li> <li>• Acknowledge intense emotions</li> </ul> <p><i>Exploration of the beliefs related to:</i></p> <ul style="list-style-type: none"> <li>• Challenges</li> <li>• Griefs</li> <li>• Fears</li> <li>• Changes</li> </ul> <p><i>Valuing family strengths</i></p> <ul style="list-style-type: none"> <li>• Family level</li> <li>• Individual level</li> </ul>	<p>Phases 1-2-3 and Follow-up <i>Family Meeting</i></p>
<p><i>Individualized information for family</i> <i>Related to: Cognitive domain</i></p>	<p>Individualized information to family regarding their concerns and priorities, with daily information on patient clinical evolution and treatment, daily routine, and administrative aspects.</p>	<p>To empower families about the situation of their loved one, so that they can make informed decisions and cope with the uncertainty.</p>	<p><i>Verification of the comprehension and needs of information</i></p> <ul style="list-style-type: none"> <li>• Concrete facts about daily care of the patient</li> <li>• Organizational information about the hospitalization</li> <li>• Internal and external resources of the healthcare setting</li> <li>• Administrative aspects</li> </ul> <p><i>Developing new rituals</i></p> <ul style="list-style-type: none"> <li>• Pictures</li> <li>• Items (music, smells)</li> <li>• Family activities</li> </ul> <p><i>Recognize the expertise of the family</i></p> <ul style="list-style-type: none"> <li>• Knowledge about patient preferences</li> <li>• Integration of existing family routines</li> </ul>	<p>Phases 1-2-3 and Follow-up <i>Family Meeting</i></p>
<p><i>Family Engagement in care</i> <i>Related to: Behavioral, affective and cognitive domain</i></p>	<p>Including family in care by supporting family routine with inclusion of family habits or new routine in a safe way.</p>	<p>To develop a practical planning for families to be able to participate in the care they are willing to undertake</p>	<p><i>Orientation in the healthcare system</i></p> <ul style="list-style-type: none"> <li>• Identify the interprofessional team and roles of each member.</li> <li>• <i>Sharing oral and written information</i></li> <li>• Interprofessional communication including transmission with physician, head nurses, specialized nurses, coordination nurse, physical and occupational therapist, neuropsychologist (inside and outside the hospital)</li> </ul>	<p>Phases 1-2-3 and Follow-up <i>Briefing</i> <i>Family Meeting</i> <i>Debriefing</i></p>
<p><i>Interprofessional collaboration and care coordination</i> <i>Related to:</i> <i>cognitive and interprofessional (additional) domains</i></p>	<p>Care coordination regarding discharge planning, nursing and medical staff turnover; the interactions with other actors of the healthcare system.</p>	<p>To ensure continuity of care and information consistency within the interprofessional team and the family.</p>		

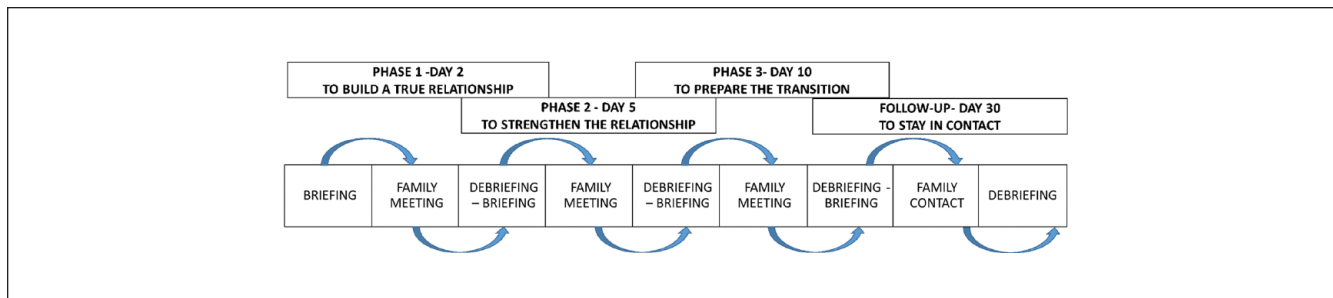


Figure 2. Matrix of the intervention delivery process.

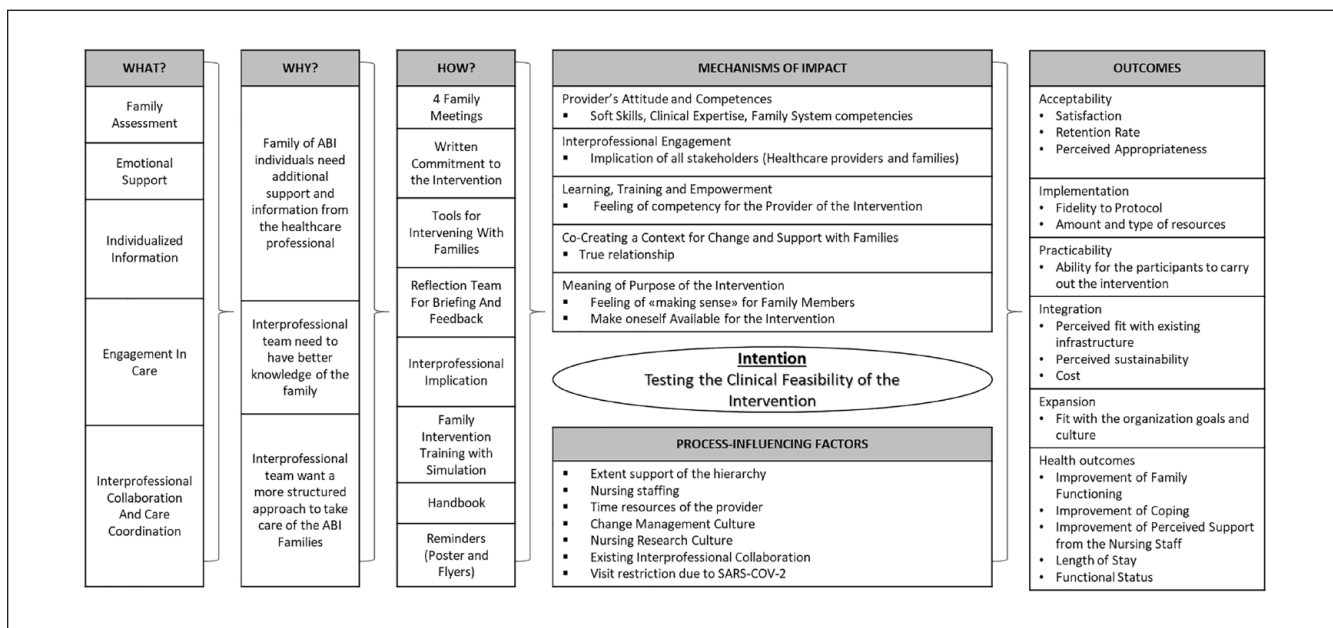


Figure 3. Logic model of the SAFIR<sup>®</sup> intervention. Note. ABI = Acquired brain injuries.

**Logic model of SAFIR<sup>®</sup>.** The Logic Model (Figure 3) displays the final version of the new complex intervention SAFIR<sup>®</sup>. It shows the key elements, their activation mechanisms of impact, and the process-influencing factors of the SAFIR<sup>®</sup> intervention. It also shows the determined outcomes for testing the acceptability and feasibility of SAFIR<sup>®</sup> in the next phase of the MRC Framework, namely the Phase 2 “Testing the Feasibility of the Intervention.” In order to respect the methodology of the MRC, a feasibility design was chosen; thus, most of the expected outcomes of this phase will be process outcomes, based on Bowen’s definition of feasibility and acceptability (Bowen et al., 2009). Nevertheless, we hope to see a trend in effectiveness on persons with ABI-related outcomes (Functional Status and Length of Stay) and on the two family-related outcomes highlighted in our systematic scoping review (Family-Functioning and Coping),

on the relation between HCPs (specifically on nurses) and families (Perceived support), as promoted by FSN.

### Discussion

This paper describes the developmental process of a new evidence-based early intervention to support families of persons suffering from ABI. This process resulted in the SAFIR<sup>®</sup> intervention, a CNS-led intervention including five core components and structured around three phases and a follow-up. The complete description of the intervention aimed to fulfill the “black boxes” of nursing intervention development. The TIDieR checklist and GUIDE helped in the reporting of guarantee that all the elements are presented clearly as well as how they are activated using the Logic Model. Both FSN, specifically CFAM and CFIM, and the MRC

Framework were also valuable guides used to successfully reach our main goal. FSN assisted us in developing the intervention core components and tailoring the process. The collaborative approach warranted the adjustment of every intervention characteristics to our real-life context and population. The MRC Framework was relevant in rigorously assessing every step of the process, by searching the available evidence for family needs and family-oriented interventions, by identifying the best theoretical assumption corresponding to our aim, and by modeling the process of the intervention. In order to be more rigorous in the development phase of a new intervention, Bleijenbergh et al. (2018) proposed enriching the MRC framework by adding three steps in the first phase: Problem identification and definition, determine the needs, and examine current practice and context (Bleijenbergh et al., 2018). These adjustments support our approach to describe in-depth the development of a new intervention based on the best available evidence for the population of interest.

To the best of our knowledge, our intervention is the first early family support intervention for persons suffering from ABI. SAFIR<sup>®</sup> integrated the family as a unit. Most of the studies recorded in our previous findings focused only on the caregivers or take place in the chronic phase. A recent study testing the effectiveness of a family-centered intervention after a TBI showed no extra benefit after the intervention and recommend a systemic approach to intervene with families (Rasmussen et al., 2021). Identifying a theory in the development phase of the MRC framework allowed us to integrate a model that meets international recommendations of moving from a patient-centered care approach to a FSN approach, including the person, the whole family, the clinicians, and the environment (Montoro-Gurich & Garcia-Vivar, 2019; World Health Organization, 2016).

The SAFIR<sup>®</sup> intervention is based on theoretical and empirical findings. Regarding our theoretical findings, we highlighted a coherence between family needs in acute care and the main core components found in our systematic scoping review. Our results also demonstrated a gap to fulfilling family needs during the acute phase of hospitalization with a lack of interventions during this period. This justified the development of SAFIR<sup>®</sup> to support families of ABI persons from the early phase of hospitalization. These results follow the recommendations of previous studies in other countries regarding additional support for families of persons with ABI (Dawes et al., 2020; Kreutzer et al., 2015).

Considering FSN, we developed our intervention by addressing the relationship between nurses and families. The literature has shown that a high level of competence is necessary to lead a family intervention in a clinical setting, but that all nurses should be able to provide the best care to families (Rowat et al., 2016; Vaughn et al., 2016). This is congruent with findings related to Step 3. Thus, we followed the international recommendations regarding the standard of practice for FSN when caring for families (IFNA, 2017), including

specific education and coaching of the interdisciplinary team in order to support the CNS during this intervention. We also managed enough time between two family meetings to allow the CNS sufficient time for reflection and reflexivity (i.e., briefing and debriefing), in order to avoid *moral distress* (McAndrew et al., 2018; Russell, 2012) that HCPs may experience in critical situations of families living with an person suffering from ABI.

### **Strengths and Limitations**

Our research illustrates the complete development of a new family intervention, guided by a methodological framework (MRC Framework) and a theoretical framework (FSN). It demonstrates the complexity of the development process due to the interactions and interrelation between the different actors (the human factors), the elements of the local context (contextual factors), and the quality of the existing evidence concerning our population. Nevertheless, the use of the frameworks, as well as the reporting tools, guaranteed the reproducibility of our intervention.

Regarding the state of the science in our field of research, it was justified to carry out a systematic scoping review. This allowed us to test its acceptability. It should also be noted that the field expert sample and families were recruited from a convenience sample; the results should therefore be read considering these aspects.

### **Conclusion**

The development of a complex family intervention was an iterative and systemic process. It was made possible by the methodological framework that guided the process in detail and supported a rigorous approach, allowing the emergence of a solid body of evidence to support the development and the pilot testing of our intervention. To the best of our knowledge, this is the first time that an early family intervention for the family of those affected by ABI has been developed for and with all stakeholders. We will now have to further test this process to see whether the integration of clinicians and family's preferences has resulted in an intervention that is acceptable to HCPs and families, and whether taking contextual factors into account is a guarantee of its feasibility.

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## Supplemental Material

Supplemental material for this article is available online.

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