



End of year report

2015 Project

La Fondation Motrice

Finding practical solutions to improve the day-to-day life of
children suffering from cerebral palsy

Improving Pain Management in Cerebral Palsy

The funds provided to your organisation for the current year by TFWA Care were donated following the approval of the TFWA Management Committee and board. Among the prerequisites for funding by TFWA Care are transparency and accountability. We would be grateful if you could send us a brief summary of the project, the objectives achieved, problems encountered, impact on the local community and indicators of the project's success. We will share the report with the Management Committee at the end of year meeting.

Please do not hesitate to report on the project's successes as well as any aspects that did not go according to plan. This serves to provide a greater understanding of the challenges and issues encountered by the communities on whose behalf your organisation is working. Any quantifiable indicators will also be helpful in your report.

Thank you.



Project details

1. Please summarise in a few words the project supported by TFWA CARE, including the principle objectives and duration.

To better understand and manage pain in children and teenagers affected by Cerebral Palsy (CP) is among the key priorities of *La Fondation Motrice (LFM)*.

As a matter of fact, when *La Fondation Motrice* organized a series of focus groups to elicit views of adults with CP, families, parents, professionals and researchers on the expectations of children and adults with CP, taking care of pain ranked first to cognitive, mobility and speech impairments on the list of topics that families thought researchers and professionals should tackle.

Relying on a dedicated Steering Committee chaired by Pr O Rémy Nérès and composed of key experts in pain and Cerebral Palsy management, on both the Scientific Board and the Board of Administration of *La Fondation Motrice*, it was decided that several projects to tackle this key topic would be supported. TFWA Care agreed to co-sponsor these projects with LFM.

1/ **Study 1 QUALIDOL** (*Qualitative analysis of pain during physiotherapy in children with Cerebral Palsy. Dr S Brochard, Pediatric Rehabilitation, CHRU Brest*): This is a qualitative study whose goal was to explore the real-life experience of pain in children and teenagers with Cerebral Palsy during physiotherapy, in particular to identify the most painful moves and locations induced by physiotherapy exercises and the way they face it. This study is based on semi-directive interviews and conducted on small group of children and teenagers.

2/ In 2012, a specific call for projects entitled “**Management of pain in children and teenagers with Cerebral Palsy**” selected 3 projects:

1. **STUDY 2** (*Evaluation of pain by analysis of the parasympathetic tone: application in children with Cerebral Palsy. Dr Justine Avez-Couturier, Neuropediatrics, CHRU Lille*)
This project is related to new techniques aimed at better identifying and assessing the level of pain in children with CP who are not able to fully describe their sensations due to verbal communication difficulties.
2. **STUDY 3** (*Prevention of pain in spine surgery: validation of the use of bisphosphonates in poly-handicapped children. Dr Agnès Linglart, Pediatric Endocrinology, Hôpital Bicêtre, Paris*)
Surgery of the rachis for scoliosis is relatively frequent in children with CP. The aim of this project is to prevent, by a preoperative treatment with bisphosphonates IV, the acute pain related to scoliosis surgery in deeply osteoporotic bone
3. **STUDY 4 ANTALKINE PC** (*Antalgic treatment and physiotherapy in children with Cerebral Palsy. Pr Olivier Rémy Nérès, Pediatric Rehabilitation, CHRU, Brest*)

Physiotherapy takes a large part in the life of children with CP in order to prevent or limit the contractures and limb deformities that can occur in spastic Cerebral Palsy. However physiotherapy is sometimes considered painful by the children and teenagers. The aim of this project is to evaluate the efficacy of usually used analgesics (ibuprofen) to prevent pain in this context.

4. **In 2013, Study 5: CP COHORT (Longitudinal Study of a Children Population With Bilateral Severe Cerebral Palsy: Incidence and Evolution of Orthopaedic Complications and Pain Related With These Complications Dr I Poirot HCL Lyon).** This is an ambitious project aimed at determining the incidence of orthopaedic complications in children with severe CP and the onset with time of pain related to these complications; 385 children will be included in this French cohort and followed up for 10 years.
5. **At the end of 2014, TFWA CARE agreed to support a new project Study 6 DIS-PC (Pain and Discomfort related to care within establishments welcoming children and adults with Cerebral Palsy. Ms A Dubois CHU Brest).** The purpose of this observational study is to report the prevalence and conditions of occurrence of care-related pain and discomfort in children and adult with cerebral palsy in medical or medico- social establishment. The main aim is to identify the clinical characteristics of patients (age, type and severity of disability), the types of care-activities and the nature of the institutional admission (medical or medico-social). Secondary objectives are to identify risk factors related to the induced pain and patient characteristics, as well as to create an easy-to-use weekly continuous pain assessment tool in a routine clinical set-up.

The activities carried out by the different teams from 2012 to 2014 have been reported in our previous reports

2. What activities were carried out within the scope of the project over the course of the year?

The different activities carried out during the year 2015, by the 6 teams funded by TFWA are reported below:

- **Study 1 :QUALIDOL (S BROCHARD)**

During the year 2015 the team focussed on communicating the main results of this study in multiple meetings. They were first presented during the scientific meeting organized by *La Fondation Motrice* in March 2015 (see below). They have been presented also in French congresses (SFERHE in May as a poster and SOFMER in October as an oral communication) and will be presented during the PEDIADOL congress in December 2015 with the publication of the lecture in the congress book. An abstract has been submitted for the EACD (European Academy Of Childhood Diseases) congress in 2016 and a

manuscript submitted for publication to Physical Therapy review. Moreover this work was the basis of the medical thesis of Dr H Saudreau who is working with Dr S Brochard (December 2014).

Study 2: EVALUATION OF PAIN BY ANALYSIS OF THE PARASYMPATHETIC TONE (J AVEZ COUTURIER)

The study has been approved by the ethics committee in October 2014; In March and April 2015, meetings have been organised for the investigators and their teams in the 2 centers (Centre Marc Sautelet, Villeneuve d'Ascq et Centre Hospitalier de Zuydcotte) to launch the study. Therefore pre-inclusions and inclusions could begin. Today 5 patients have been pre-included in the study and 3 have been included.

- ***Study 3: PREVENTION OF PAIN IN SPINE SURGERY (A LINGLART)***

During this year, the missing files have been recovered and collected therefore all the files have been entered in the data base. The database has been frozen and the statistical analysis is ongoing. Abstracts are planned to be submitted to the SFP (Société Française de Pédiatrie) and SFN (Société Française de Neurologie) meetings (deadline January 2016).

- ***Study 4: ANTALKINE PC (O REMY-NERIS)***

During the year 2015, this project encountered major obstacles for administrative reasons.

After a careful writing of information forms and consents the approval of the ethic committee (CPP Ouest 6) was definitely obtained on January 15th 2015.

The funding allowed the pharmacy to prepare the procedure of drug and placebo preparation.

In parallel, the protocol was addressed to the ANSM (French national drug agency). However the ANSM did not give the authorization to produce the drug and placebo for administrative reasons. The team is trying to solve these obstacles and an administrative appeal is ongoing.

- ***Study 5: CP COHORT (I POIROT)***

As of today, 278 patients are included (18 new patients) and the study has been extended to 6 new centres. The study communication towards the investigators is regularly carried out through newsletters. An investigator meeting was held on November 2014 during the SFERHE congress (Société Francophone d'Etudes et de Recherche sur les Handicaps de l'Enfance). The team regularly participates in congresses to share on the study, and on the data collected. This enables to meet many clinicians and to share experiences and practices, in order to improve the knowledge on Cerebral

Palsy domain with the aim of offering the best life possible to these severely affected children. Oral presentations have been done during IFRH congress (Institut Fédératif de Recherche sur le Handicap) in November 2014, CDI annual meeting (Cercle de Documentation et d'Information) in December 2014. A manuscript entitled « Prevalence of pain in 240 children with cerebral palsy, levels 4 and 5 of the Gross Motor Function Classification System (GMFCS) » has been submitted to Developmental Medicine and Child Neurology. The first children included in the study are now entering their 6th year of follow-up. Therefore the data base contains more and more information. Preliminary analyses will be performed to evaluate the evolution over time of hip excentration and scoliosis.

- **Study 6 : DYS-PC (A DUBOIS)**

From January, 2015, the team has focused the study on 2 points:

1. Ethical Committee Approvals: The study was approved by the local ethics committee (Comité de Protection des Personnes Ouest I, Tours, France) and the CCTIRS (Comité Consultatif sur le Traitement de l'Information en matière de Recherche dans le domaine de la Santé). The agreement from the CNIL (Commission Nationale de l'Informatique et des Libertés) is expected soon (the recruitment of the participants cannot start without this agreement).
2. Institution selection. The recruitment of participants in 12 centers for children and 12 for adults, each in the 4 departments of the Brittany is needed in the study. The Fichier National des Etablissements Sanitaires et Sociaux (FINESS) was used to produce an exhaustive list of medical and medico-social institutions in Brittany. 169 institutions met the inclusion criteria, 69 for children and 100 for adults. Randomization is now necessary to select centers in which participants will be recruited. This point of the methodology will be achieved in few weeks.

The participant recruitment is expected to begin soon and it will start by children in the Finistère department.

Communication on these projects and on pain in Cerebral Palsy at large was stimulated and endorsed by La Fondation Motrice in different ways

- Lecture entitled "Pain and Quality of Life -Views from parents and professionals" in November 2014 during the scientific days "Journées Polyhandicap et IMC"
- Meeting with Dr I Poirot (Study 5), the medical and paramedical teams of the association ARIMC 69 and *La Fondation Motrice* on orthopaedic complications and pain on 18th December 2014 in Lyon. During this meeting, a facsimile of a bank check indicating the amount of TFWA support was given to Dr Poirot.



Dr I Poirot and Dr A Chatelin

Newsletter on the cohort study on pain related to orthopedic complications

cohorte PC LA FONDATION MOTRICE sferhe^{ts} ALLP Hôpital Civil de Lyon

Étude longitudinale d'une population d'enfants atteints d'une forme bilatérale sévère de paralysie cérébrale: incidence et évaluation des complications orthopédiques et des douleurs en lien avec ces complications

Newsletter n°25 – Juillet 2015

Un CRF repensé sur-mesure pour vous !

Le « cahier bleu » fait peau-neuve pour devenir le « cahier orange »: il a été revu et simplifié pour vous en faciliter le remplissage. Un choix a dû être fait pour ne conserver que les données jugées nécessaires pour l'étude, et ainsi vous faire gagner du temps. Le fiche Douleur, réorganisée avec votre aide à nous, a été reconstruite pour correspondre de manière plus juste à la réalité du terrain. Nous espérons que cette nouvelle version vous apporte satisfaction, et nous comptons sur vous pour un remplissage le plus complet possible, afin d'éviter en retour les demandes de correction.

→ Pour vos prochaines inclusions (AD0), vous pouvez dès maintenant contacter Valérie pour recevoir de nouveaux cahiers.
→ Pour les visites annuelles (AD1 et suivantes): complétez les visites sur les anciens CRF que vous avez déjà reçus; vous recevrez les nouveaux CRF pour vos futures visites.

RAPPEL IMPORTANT – LES BASSINS DE VOS PATIENTS :
Les mesures des radios du bassin et du rachis sont le Critère de Jugement Principal de l'étude. Nous avons besoin des photos de ces radios pour alimenter la base de données de la cohorte.
→ Les photos des radios du bassin et du rachis sont systématiquement à transmettre par mail à l'ARC après chaque visite de vos patients. Merci d'avance pour votre collaboration !

Bilan des inclusions: où en est-on ?

→ Parmi les 51 Centres investigateurs, 5 Centres n'ont pas encore inclus de patients.
→ Il reste un peu plus de 100 patients à recruter avant fin 2016... COURAGE !
→ 29 patients de retard par rapport aux inclusions théoriques: il suffit d'un petit effort collectif pour atteindre notre objectif !
→ Tout nouveau centre est le bienvenu, et a encore 1 an et demi pour nous aider à recruter les patients. N'hésitez pas à parler de l'étude autour de vous !

Aidez-nous à pérenniser la cohorte !

Afin d'assurer les 10 années de suivi par patient prévu dans la cohorte, nous avons été contraints de diminuer le temps personnel sur l'étude: le temps ARC est passé de 100 % ETP à 20 % ETP → Nous devons vous laisser plus autonomes. Nous restons bien entendu toujours disponibles pour toutes vos questions et demandes: n'hésitez pas à nous contacter ! Valérie reste votre interlocutrice; vous pourrez désormais le joindre le lundi, le mardi, et le jeudi matin.

Note: Les relances des prochaines visites à programmer vous seront dorénavant transmises annuellement.

Financements

Nous avons soumis la candidature de l'étude à 3 Appels d'offre (Fondation de France, Fondation Motrice, et ALLP), et espérons que nous parviendrons à obtenir des financements complémentaires pour continuer à faire vivre la cohorte. Nous attendons les résultats d'ici la fin de l'année.

Attachée de Recherche Clinique: valerie.laurent@chu-lyon.fr - Tél: 04 72 35 77 22 / Investigateur Coordonnateur: juliette.garnier@chu-lyon.fr
Centre d'Investigation Clinique: Tél: 04 72 35 72 31 - Fax: 04 72 35 72 64

- In March 2015, organisation by *La Fondation Motrice* of a 2-day scientific meeting dedicated to the progresses achieved in the research on Cerebral Palsy during the past 10 years. During a specific session devoted to the identification and the management of chronic pain, the floor was given to the teams supported by TFWA to share their projects. These scientific days gathered 200 attendants: medical and paramedical teams, researchers, associations, institutions, parents and persons with CP coming from France and Europe.

During this meeting, a facsimile of a bank check indicating the amount of TFWA support was given to Ms A Dubois.

Scientific meeting La Fondation Motrice (March 2015)



Video on pain : feelings of people with CP



Session on pain : expert panel



Dr S Brochard



Dr J Avez-Couturier



Dr A Dubois, laureate of La Fondation Motrice

SOUS LE HAUT PATRONAGE DE MADAME SÉGOLÈNE NEUVILLE, SECRÉTAIRE D'ÉTAT
CHARGÉE DES PERSONNES HANDICAPÉES ET DE LA LUTTE CONTRE L'EXCLUSION

Les Journées de La Fondation Motrice Recherche sur la Paralysie Cérébrale



2005-2015

UNE DÉCENNIE DE PROGRÈS

VENDREDI 13 ET SAMEDI 14 MARS 2015

Institut Pasteur - Amphithéâtre du CIS - 28 rue du Docteur Roux Paris 15^e

Stratégies de douleur chronique · Stratégies de prévention · Nouvelles approches en
remédiation · Progrès en imagerie cérébrale dans l'AVC néonatal · Recommandations

PROGRAMME
au 20/02/2014

Vendredi 13 mars 2015

14h00 RECONNAÎTRE, DÉFINIR ET TRAITER LA DOULEUR CHRONIQUE : Un axe de recherche clé de la Fondation Motrice

Modérateurs : Dr Isabelle POIROT (HFME L'Escalier, Bron) et M. Christian MINET (AAIMC de la Région Champagne-Ardenne, Reims)

Court-métrage II - La douleur au quotidien

La douleur chez l'enfant et l'adolescent : données de l'étude SPARCLE

Dr Catherine ARNAUD (CHU Toulouse, Toulouse)

Douleur induite par la kinésithérapie : qu'en pensent les enfants ?

Dr Sylvain BROCHARD (CHU Morvan, Brest)

Évaluation de la douleur par analyse des variations du tonus parasympathique : applicabilité chez l'enfant atteint de Paralysie Cérébrale

Dr Justine AVEZ COUTURIER (CHRU de Lille, Lille)

Prise en charge antalgique : quels moyens ?

Dr Élisabeth FOURNIER CHARRIÈRE (Hôpital de Bicêtre, Kremlin-Bicêtre)

Prise en charge non médicamenteuse : place de la kinésithérapie

M. Philippe TOULLET (Institut Motricité Cérébrale, Paris)

Discussion - Échanges avec la salle

Modérateurs et orateurs de session

- Contribution to the forum "Douleur et Handicap - La douleur chez les personnes en situation de handicap moteur d'origine cérébrale à travers les âges de la vie » organized by the Union Régionale IMC-PC Bretagne with the participation of Dr S Brochard and Pr O Remy-Néris (April 2015)

Evaluation

3. Has the project been successful? Please outline the success factors for each objective as well as the challenges encountered and solutions adopted to overcome them.

As reported in the previous section, 2 projects (Study 1 and 3) are on track and are quite successful. The team leaders are fully involved and the results of study 1 have been delivered and will be soon published. The first presentation of the results of study 3 are expected soon (early 2016).

Study 2 has achieved its 2015 goal with the beginning of inclusions.

Study 5, thanks to the complementary funding has nearly reached its 2015 recruitment target.

Study 6 is on track for a recruitment in early 2016.

Only study 4 ANTALKINEPC has been notably delayed due to administrative difficulties despite the involvement of the principal investigators and the pharmacist in finding solutions.

For all these projects, the involvement of the principal investigator and of his/her team, the investigator meetings and newsletters are key levers for the progress of the projects.

4. Did the work accomplished this year help you learn lessons that will benefit future work?

The multiple communications on pain towards the organisations taking care of persons with CP revealed a real need for actions and projects specifically dedicated to young adults who are also suffering from pain. A future call for projects in this specific population could be considered.

Sustainability

5. How has the project had a positive impact on the community/ies at the core of the project and what will be the long term benefits? Please explain if the project has helped empower the beneficiaries by providing greater autonomy.

The communication organised by *La Fondation Motrice* especially during its scientific days in March 2015 on management of pain have led to a greater awareness in the scientific community (doctors, physiotherapists, researchers) on the importance of pain in the daily life of children and teenagers, as well as the need for better management. We have noticed that in many meetings on Cerebral Palsy a (higher number of lectures devoted to pain that could be the consequence of the work supported by LFM and TFWA. Consequently, this should lead to improved recognition and daily management of pain in people with CP from now on. Associations of families have acknowledged the increased awareness by carers on pain in children with CP due to the continuous work by *La Fondation Motrice* on this major concern.

6. Will the project continue in the future or is it now complete? Will further funding be required in the future to complete the work? Please indicate if the initial funding request was a multi-year project. ** (see footnote)

These projects will continue in the future. According to their current status, recruitment, analysis of data or publications/oral communications are expected in 2016.

Finance



7. Please provide a summarised breakdown of how TFWA Care funds were utilised for the project.

TFWA CARE funds received were of 35,000€ in 2012, 38,000€ in 2013, 38,600 € in 2014 and 40,150€ in 2015 i.e. a total of **151,750 €**. As noted in our previous reports (2012/2013, 2013/2014 and 2014/2015) the allocation of the funds was the following:

- 2,500 € allocated to the QUALIDOL study. A contract was signed between *La Fondation Motrice*, Pr O Rémy Néris and the Hospital of Brest in September 2012.
- 56,000 € allocated to fund the 3 projects selected from the call for projects in December 2012. Contracts were signed between *La Fondation Motrice* and the 3 laureates (Dr J Avez-Couturier, Dr A Linglart and Pr O Rémy Néris). Half of the grant was paid at the signature of the contract for the 3 laureates. The other half was paid at the end of 2013 for 2 laureates (Dr J Avez-Couturier, Dr A Linglart) based on an interim report detailing the course of the projects. For the 3rd laureate (Pr O Remy Neris), the payment will be made at the time of the 1st inclusion in the study.
- 33,600 € allocated to fund the CP cohort. A contract was signed between *La Fondation Motrice* and Dr I Poirot. Half of the grant was paid at the signature of the contract and the other half was paid in November 2014 based on an interim report detailing the course of the project.
- 36,500€ allocated to fund A Dubois A contract was signed between *La Fondation Motrice* and Ms A Dubois. Half of the grant was paid at the signature of the contract and the other half I was paid in Ocotber 2015 based on an interim report detailing the course of the project.
- 8,450 € for the communication on the selected projects to the scientific community
- 14,700 € (≈11% of the total amount) dedicated to the administrative costs of La Fondation Motrice related to the management of the selected projects

The use of these funds, at the time of this report is summarized in the table below.

	2012	2013	2014	2015	Total 2012-2015 (November)	To be paid 2016
STUDY 1 QUALIDOL O Rémy-Néris/S Brochard (Brest)	2,5				2,5	
STUDY 2 EVALUATION OF PAIN J Avez-Couturier (Lille)		14			14	
STUDY 3 PAIN IN SPINE SURGERY A Linglart (Kremlin Bicêtre)		16			16	
STUDY 4 ANTALKINE PC O		13			13	13

Rémy Nérés (Brest)						
STUDY 5 CP COHORT <i>I Poirot (Lyon)</i>			33,6		33,6	
STUDY 6 DYS-PC <i>A Dubois (Brest)</i>				36,5	36,5	
Communication STUDY 5 <i>CP COHORT</i> <i>I Poirot (Lyon)</i>			1,45		1,45	
Communication LFM		5	2		7	
Administration LFM	4,5	5	1,55	3,65	14,7	
TOTAL	7	53	38,6	40,15	138,75	13

Funds from 2 other donors have been also allocated to these projects, but TFWA CARE remains the major partner of *La Fondation Motrice* in supporting more than 80% of the total costs of the project “Improving pain management in Cerebral Palsy” allowing *La Fondation Motrice* to fully conduct this project.

Please attach your latest annual report as well as any pictures you would like to use to illustrate this report.

We would be grateful if you could send this to John Rimmer (j.rimmer@tfwa.com) by **November 6 2015 at the latest.**



** If you would like to submit a request for further funding for a **new project** to be funded by TFWA CARE in 2016, please complete the form on the following page.

SUMMARY

In April 2015, *La Fondation Motrice* has launched a new call for projects in order to sustain its support to research and clinical teams in the Cerebral Palsy domain. Rehabilitation is very important during the life of children and adults with CP to help them to live with their motor or cognitive deficiencies. To potentially support the development of good practice guidelines in rehabilitation, *La Fondation Motrice* will provide grants for projects that would bring additional research in the field of motor or cognitive rehabilitation in persons with CP. Among the 20 letters of intent which have been received in June 2015, the Scientific Committee selected 11 projects. These projects have been submitted more in detail to the Scientific Committee (evaluation ongoing) and some of them will be therefore selected to be funded in 2016 by *La Fondation Motrice*.

Among these 11 projects, one of them has the objective to evaluate the effectiveness of integrating gaming into standard physiotherapy sessions as to help achieving individual goals in non- walking/ not independently ambulant children with CP.

A financial support from TFWA for this project would be of high importance :

- to help finding practical solutions to improve the day-to-day life of children suffering from cerebral palsy
- to support our work on rehabilitation.