

BellPIC

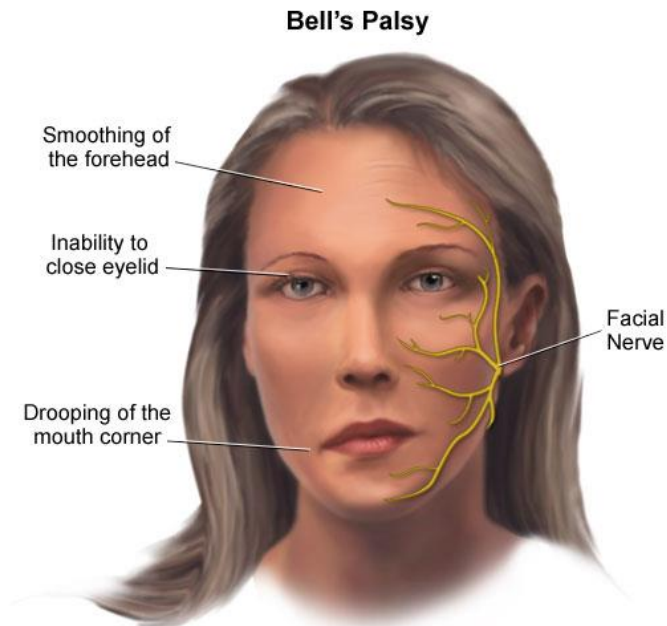
Bell's Palsy in Children Study

Bell's palsy in Children (BellPIC)

- Lead site: Royal Children's Hospital / Murdoch Children's Research Institute, Melbourne
- 10 PREDICT centres:
 - **Victoria:** RCHM, Monash Medical Centre, Sunshine
 - **New Zealand:** Starship Hospital Auckland
 - **NSW:** Westmead Children's Hospitals; John Hunter Children's Hospital, Newcastle
 - **WA:** Princess Margaret Hospital, Perth
 - **QLD:** Lady Cilento Children's Hospital, Brisbane, Gold Coast Hospital
 - **SA:** Women's and Children's Hospital, Adelaide
- National Health and Medical Research Council (NHMRC) funded (\$1,100,000)

What is Bell's Palsy?

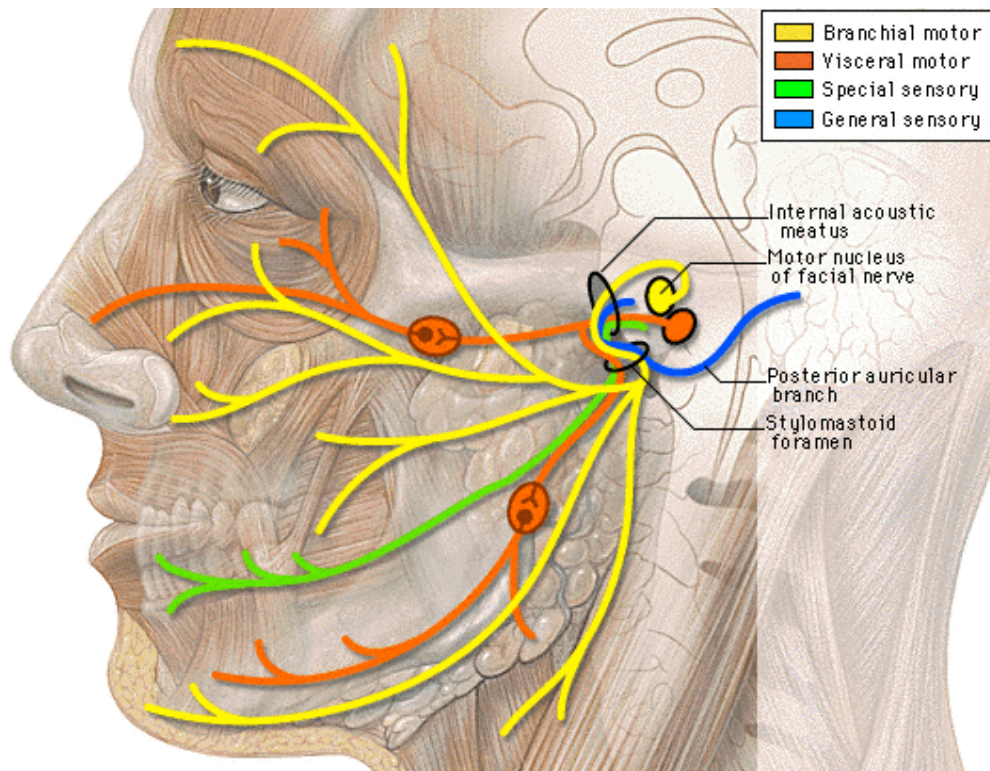
- Sudden onset unilateral weakness of the facial muscles
- Caused by impairment of the peripheral facial (7th) nerve
- Cause unclear – presumed idiopathic, immune mediated



Hopkinsmedicine.org

What is Bell's Palsy?

Facial nerve supplies: muscles of facial expression, taste tongue, muscles of hearing, salivary and lacrimal glands



Component Overview

The facial nerve has four components with distinct functions:

Branchial motor (special visceral efferent)	Supplies the muscles of facial expression; posterior belly of digastric muscle; stylohyoid, and stapedius.
Visceral motor (general visceral efferent)	Parasympathetic innervation of the lacrimal, submandibular, and sublingual glands, as well as mucous membranes of nasopharynx, hard and soft palate.
Special sensory (special afferent)	Taste sensation from the anterior 2/3 of tongue; hard and soft palates.
General sensory (general somatic afferent)	General sensation from the skin of the concha of the auricle and from a small area behind the ear.

What is NOT Bell's Palsy?

- Abnormality of the facial (7th) nerve due to other, known causes
 - Facial trauma (history or signs of trauma)
 - Otitis media (fever, pain, abnormal tympanic membrane)
 - Herpes zoster (blisters in ear canal)
 - Brain tumour or other central nervous processes
=> central (headaches, other neurological findings)

How to Differentiate Central vs Peripheral Facial (7th) Nerve Palsy?

Peripheral 7th palsy (such as Bell's palsy):

- Fibres for forehead cross over- so unable to wrinkle forehead on affected side

Central 7th palsy (such as due to brain tumour):

- Still able to wrinkle forehead on affected side

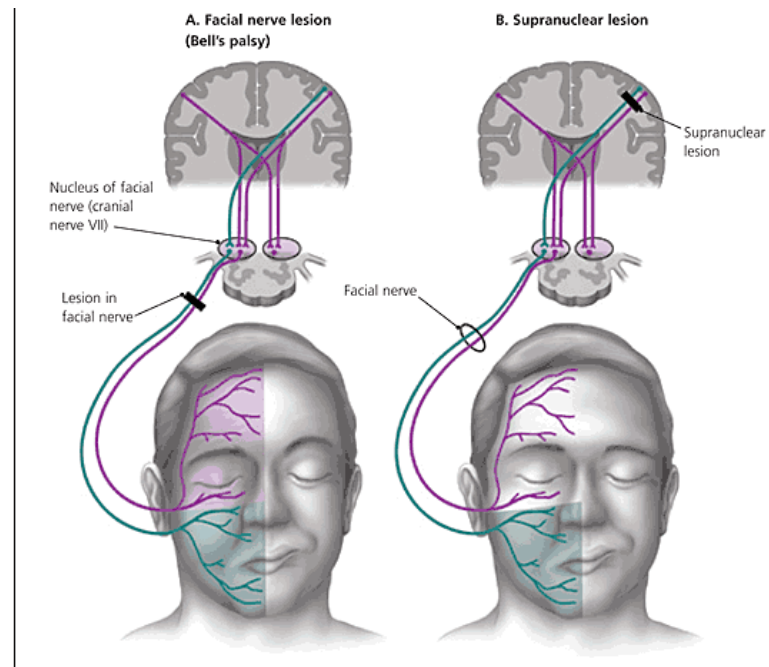


Figure 2.

Patients with (A) a facial nerve lesion and (B) a supranuclear lesion with forehead sparing.

Bell's Palsy in Children

- 60% of children recover by 1 month (without steroids)
- >90% of children recover within 12 months

HOWEVER these children suffer with issues such as,

- Prolonged functional impairment:
 - Unable to close mouth > impacts eating and speech
 - Eye closure/ drying
- Emotional impact of disfigured face & communication
- Problems after healing (*synkinesis*- misconnection of nerves)
 - Crocodile tears or corneal drying
 - Involuntary facial movement, facial spasm
 - Pain

Bell's Palsy Treatment

In adults there is high level evidence that

**Prednisolone improves recovery in Bell's palsy
(and antivirals do NOT work)**

Two recent studies:

50 mg per d x 10 d, no taper, vs placebo
83% vs 63% recovery by 3 months

Sullivan NEJM 2007

60 mg per d x 5 d, then taper x 5 d, vs placebo
62% vs 51% recovery by 3 months

Engstrom Lancet Neuro 2008

Bell's Palsy Treatment - Children

- No similar high level data in children
- One RCT in children but no placebo, small numbers
1 mg/kg/d prednisolone equivalent x 10 days vs nil
86% vs 72% recovery at 4 months
All patients fully recovered by 12 months
Ünüvar Ped Neurology 1999
- Almost all paediatric patients eventually recover
- Currently only 50% of children treated with prednisolone

Bell's Palsy Guidelines

In adults: American Academy of Neurology (2012)

- Steroids have proven efficacy, no further studies needed

In children: no published national or international guidelines

- RCH Melbourne:

The role ...of steroids in Bell's palsy in children is unclear, however steroids appear to benefit adults, particularly if given < 72 hours and if complete palsy present. Prednisolone (1mg/kg/day PO daily for 10 days) may be considered for Bell's palsy presenting < 72 hours.

BellPIC Study

Research question:

Does PO prednisolone increase recovery from Bell's palsy in children at ***1 month*** compared with placebo?

What is the BellPIC Study?

- Blinded placebo controlled trial
- ***Prednisolone*** 1 mg/kg (max 50 mg) ***vs placebo***
- Children aged ***6 mo to <18 yrs*** with Bell's palsy
- Emergency department only
- ***270 children*** in each group (540 total)
- Over ***4 year*** period at ***10 centres***

BellPIC Study

Inclusion criteria:

- Aged 6 months to < 18 years
- Weight \geq 5kg
- Be diagnosed with Bell's palsy by their treating doctor
- Have acute onset of symptoms of Bell's palsy for ***less than 72 hours*** prior to randomisation

Exclusion criteria:

1. Likely to be unable to complete the 1 month study assessment of Bell's palsy symptoms. Where the participant is unable to attend the study site, the assessment can be completed via videoconferencing using skype software or other online tools.
2. Previously randomised into the study.
3. Contraindication to prednisolone, including: active or latent tuberculosis, systemic fungal infection, known hypersensitivity to prednisolone or any of the excipients in the liquid, diminished cardiac function, diabetes mellitus, peptic ulcer or chronic renal failure, multiple sclerosis, recent active herpes zoster or chickenpox.
4. Use of any systemic or inhaled steroid within 2 weeks prior to the onset of symptoms.
5. Current or past oncological diagnosis
6. Pregnancy.
7. Breast feeding.
8. Currently receiving concomitant medications in which prednisolone is contraindicated.
9. Immunisation with a live vaccine within the previous 1 month.
10. Requirement for a live vaccine within 6 weeks of the first dose of study drug.
11. Signs of upper motor neurone VII nerve palsy (weakness of the lower half of the face only).
12. Diagnosis by a medical doctor of acute otitis media concurrently or within 1 week prior to the onset of Bell's palsy symptoms.
13. Evidence of vesicles on the ear drum suggestive of herpes simplex related Ramsay Hunt syndrome.
14. Known facial trauma within 1 week prior to the onset of symptoms that in the view of the clinician may have caused or contributed to facial palsy.
15. Any other condition at risk of being influenced by the study treatment or that might affect completion of the study.
16. Any concern regarding parent/guardian/participant ability to comply with the study protocol.

Primary outcome:

- Complete recovery per House-Brackmann scale at 1 month
- Will be assessed by a neurologist/specialist paediatrician/emergency consultant

Step 1: Inclusion/Exclusion

- Patient presents with facial weakness and is diagnosed with Bell's Palsy
- During hours Research team is notified, after hours, ED Doctor completes
- Retrieve CRF 1 from BellPIC box and ensure patient meets all inclusion criteria and no exclusion criteria

CRF 1 : ELIGIBILITY FORM

Date: / / Form completed by: _____

INCLUSION CRITERIA- all 4 required to be included

- Aged between 6 months to *less than* 18 years
- Weight \geq 5kg
- Diagnosed with Bell's Palsy
- Have acute onset of symptoms of Bell's palsy (hemifacial weakness) for <72 hours prior to presentation

EXCLUSION CRITERIA (tick all that apply)- any exclusion criteria present=> excluded

- Previously **randomised** in BellPIC study
- Contraindication to prednisolone: active or latent tuberculosis, systemic fungal infection, known hypersensitivity to prednisolone, diminished cardiac function, diabetes mellitus, peptic ulcer or chronic renal function, multiple sclerosis or recent active herpes zoster or chickenpox.
- Use of systemic or inhaled steroid within 2 weeks prior to the onset of symptoms
- Current or past oncological diagnosis
- Pregnancy and/or lactating
- Currently receiving medications for which prednisolone is contraindicated
- Immunisation with a live vaccine within the previous 1 month
- Requirement for live vaccine within 6 weeks of first dose of prednisolone
- Signs of upper motor neuron VII nerve palsy (weakness of lower half of the face only)
- Current or recent (1 week prior to Bell's palsy symptoms) otitis media
- Evidence of vesicles on the ear drum suggestive of herpes zoster
- Known significant facial trauma within 1 week prior to symptoms appearing
- Referred to GP clinic in Emergency Department or failed to wait

If **all inclusion criteria** & no exclusion criteria are present, please consent for the study
Please turn page over and follow instructions

If **any of exclusion** criteria selected, the patient is **not appropriate** for BellPIC study. Please place form in the study box.

Ensure patient meets **ALL** inclusion criteria

And **NO** exclusion criteria

Instruct clinicians to follow these instructions

Instructions regarding consent process

2 separate consent packs:

- < 12 years: **parent** information and consent
- >12 years: **parent** consent **&** **patient** consent

- Please choose the correct Consent Pack:
- Children <12 years: parent information statement and consent
 - Children >12 years: parent consent **and** patient consent

Please allow Parent/Patient time to read the Information Statement and answer any questions they may have about the study.

Once all question have been answered, please gain consent- ensure consent form is signed appropriately, including witness signature

Has Informed Consent been obtained?

YES

NO

Tick the reason consent was not obtained:

Parents refused.

Reason for refusal _____

Parents not available

Other (specify) _____

If consent has been obtained:

Step 1: Ensure consent form is signed appropriately:

Signatures required from patient/parent, yourself (clinician) & witness (any ED staff including clerks)

Step 2: Photocopy consent & give the copy to family.

Step 3: Place original consent form in BellPIC study box.

Step 4: Place BellPIC study enrolment sticker in patient history.

Step 5: Collect the study paperwork (next in numerical order)

Please fill out CRF 2

Once parent has signed, photocopy this.
Give the photocopied copy to the parents for their records and file the original in your BellPIC consent folder.

Optional consent for photos/videos



CONSENT FORM

HREC Study Number: HREC 35035A

Research Study Title: Bell's Palsy in Children (BELLPIC)

- I have read, or had read to me in my first language, the information statement version listed above and I understand its contents.
- I believe I understand the purpose, extent and possible risks of my child's involvement in this study.
- I voluntarily consent for my child to take part in this research study.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand that this study has been approved by The Royal Children's Hospital Melbourne Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007) – including all updates.
- I understand I will receive a copy of this Information Statement and Consent Form.

OPTIONAL CONSENT

<input type="checkbox"/> I do	<input type="checkbox"/> I do not	Consent for photos and videos to be taken of my child
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Child's Name

Parent/Guardian Name

Parent/Guardian Signature

Date

Name of Witness to Parent/Guardian's
Signature

Witness Signature

Date

Declaration by researcher: I have explained the study to the parent/guardian who has signed above, and believe that they understand the purpose, extent and possible risks of their child's involvement in this study.

Research Team Member Name

Research Team Member Signature

Date

Note: All parties signing the Consent Form must date their own signature.

What happens next....

- The doctor or RA will then pick up a study pack
- All study packs will be numbered in numerical order
- This number will correspond with the study drug pack
- So, if you pick up the pack RCH002, you would also pick up the medication RCH002.
- This number becomes their randomisation/study number

CRF 2

- All the instructions on how to complete the study can be found on CRF 2.
- Please familiarise yourself with CRF 2

Study Number: RCHM (Research Staff only)

CRF 2 : RANDOMISATION FORM (AUS)

Basic demographics and information about
current illness

This illness:

2.1 Length of illness: days hours Unknown (but <72hrs)

*estimated from when the facial palsy was first noticed

2.2 Weight: kgs

2.3 Side of the facial palsy: Left Right

2.4 Does the eardrum appear normal (ie. no otitis media, etc) Yes No

2.5 Does the patient have any face or head pain: Yes No

2.5.1 **Pain scale** (please circle appropriate number):

*Parents to fill in VAS, child to fill in faces pain scale.



This is the House Brackmann (HB) facial grading scale. Instruct the Doctors to read carefully and choose which one they think suits the patient.

We use the HB scale as our primary outcome (complete recovery from Bell's palsy = HB 1)

Synkinesis is lighter as it is not usually apparent in the early phases of Bell's Palsy

We are also asking the patient/parent what their perception of the facial weakness is. The "HB Lay" (specially designed in plain language for parents) should be provided to the parents and they should then choose a grade that suits their child

Study Number: RCHM

Please use the following scales to assess the degree of facial palsy

2.11 **House Brackmann Scale** (circle the appropriate grade):

GRADE	DEFINITION
1	Normal symmetrical function in all areas
2	Slight weakness noticeable only on close inspection. Complete eye closure with minimal effort. Slight asymmetry of smile with maximal effort. Synkinesis barely noticeable; contracture or spasm absent
3	Obvious weakness, but not disfiguring. May not be able to lift eyebrow. Complete eye closure; strong but asymmetrical mouth movement with maximal effort. Obvious, but not disfiguring synkinesis, mass movement or spasm
4	Obvious disfiguring weakness. Inability to lift brow. Incomplete eye closure and asymmetry of mouth with maximal effort. Severe synkinesis, mass movement, spasm
5	Motion barely perceptible. Incomplete eye closure, slight movement of corner of mouth. Synkinesis, contracture and spasm usually absent
6	No movement; loss of tone; no synkinesis, contracture or spasm

Synkinesis* (abnormal re-wiring of the nerves when healing): will usually **not be a clinical issue in ED. This will develop later in Bell's Palsy

2.12 **House Brackmann- Parent Perception.**

Please provide the parent/patient with the House Brackmann Lay form (attached) and ask the parent to choose which grade of facial severity they believe their child is (tick one only)

1 2 3 4 5 6

CRF 2

Provide this to the parent and allow sufficient time to read through and choose a grade. You may assist the family

Dear parent,

Please read through the following and choose which grade you think suits your child's facial palsy the best:



GRADE	SIGNS/SYMPTOMS
1	<p>Normal movement of her/his face as shown by:</p> <ul style="list-style-type: none"> - She/he can close eyes fully - She/he smiles normally - She/he has normal movement of the face
2	<p>Slight weakness in facial movement when looking very closely as shown by:</p> <ul style="list-style-type: none"> - When she/he smiles widely - there is a slight difference in one side of the mouth - She/he can close eyes fully with almost no effort - Abnormal extra movement of face muscles can barely be seen.
3	<p>Obvious weakness in facial movement but she/he appears normal at rest as shown by:</p> <ul style="list-style-type: none"> - She/he may not be able to lift both eyebrows - When she/he smiles widely there is a noticeable difference on the weak side of the mouth - She/he can close eyes fully but with effort on the weak side - Abnormal extra movement of face muscles is obvious.
4	<p>Obvious weakness of her/his facial muscles (but appears normal at rest) as shown by:</p> <ul style="list-style-type: none"> - She/he cannot lift the eyebrow on the weak side - She/he is unable to close eye fully on the weak side - She/he has an uneven smile – with even a small smile. - Abnormal extra movement of muscles of the face is severe.
5	<p>There is almost no movement of her/his face (and is abnormal at rest) as shown by:</p> <ul style="list-style-type: none"> - She/he cannot lift the eyebrow on the weak side - She/he is unable to close eye fully on the weak side - She/he has only slight movement of the mouth when smiling
6	<p>There is no movement of one side of her/his face as shown by:</p> <ul style="list-style-type: none"> - She/he is unable to lift eyebrow on the weak side - She/he cannot close eye on the weak side - She/he is unable to move one side of the mouth when talking or smiling

The Sunnybrook Facial Grading System is a little more complicated than the HB scale. Instruct doctors to circle numbers in each section. The research team will then add up the scores later.

Study Number: RCHM

2.8 Sunnybrook Facial Grading System:

Please circle/tick the appropriate boxes and numbers. You *do not* need to calculate a score, this will be completed by the research team at a later date.

Instructions:

Step 1: Complete the *Resting Symmetry* by comparing facial weakness to normal side

Step 2: Complete the *Symmetry of Voluntary Movement* by comparing facial weakness to normal side. Choose from 1-5 on each line

Resting Symmetry		Symmetry of Voluntary Movement					
Compared to normal side		Degree of muscle EXCURSION compared to normal side					
Eye (choose one only)	normal	0					
	narrow	1					
	wide	1					
	eyelid surgery	1					
Cheek (naso-labial fold)	normal	0					
	absent	2					
	less pronounced	1					
	more pronounced	1					
Mouth	normal	0					
	corner dropped	1					
	corner pulled up/out	1					
			Unable to initiate movement/no movement	Initiates slight movement	Initiated movement with mild excursion	Movement almost complete	Movement complete
		Standard Expressions					
		Forehead Wrinkle	1	2	3	4	5
		Gentle eye closure	1	2	3	4	5
		Open mouth smile	1	2	3	4	5
		Snarl	1	2	3	4	5
		Lip Pucker	1	2	3	4	5

We require photos and videos of all children

This will be reviewed by an independent
neurologist who will decide a HB grade that will
be compared against what the Dr chose

See next slide for further information

Study Number: RCHM

2.9 Facial Photos or Videos

Step 1: Please get the **ipod** out of the **ConSEPT** study box (**resus** annex).

Step 2: Take a **photo of the patient's study number** (above) so that we can identify the child in the future

Step 3: Please follow the next boxes according to the child's ability to follow commands:

Children old enough to follow commands:

We require both photos and videos

Photos:

We require 4 poses:

- At rest (eyes open, no expression)
- Smiling
- Eyes closed tightly, clenched
- Raised eyebrows
(Note: all of poses 2-4 are highly exaggerated, 'forced')

Please follow the below examples:



Videos:

Please ask the child to perform all 4 poses again and film the child's face whilst they complete them

Children not able to follow commands:

We only require a video

Please take a video of the child's face- we need to be able to see the level of facial palsy. The video should include the child actively trying to move their face ie. **opening** mouth, closing eyes, crying or **smiling**.

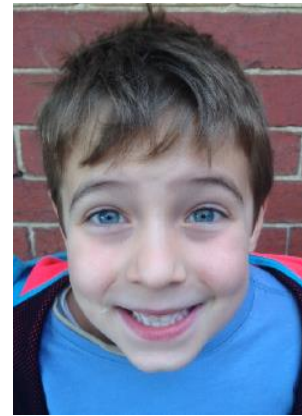
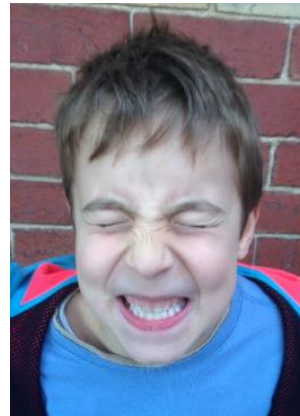
Please take as many videos as you feel necessary to capture facial movement.

Step 3: There is no need to save the photos, they will save automatically. Please close the tablet and return to the study box.

We require 4 poses:

- Eyes open (no expression)
- Smiling
- Eyes closed tightly, clenched
- Raised eyebrows

Note: poses 2-4 are highly exaggerated and forced



Video Instructions

For children who are able to follow commands:

Please film the child completing the previous 4 poses

- Eyes open (no expression)
- Smiling
- Eyes closed tightly, clenched
- Raised eyebrows

For children too young to follow commands:

Please take a video of the child's face. We need to be able to see the level of palsy. The video should include the child actively trying to move their face. For example, smiling, laughing, opening mouth, closing eyes, crying, looking up (to raise eyebrows) or looking down.

**** We need to capture the 4 poses above by asking the child to do things. Film as many times as you want, we can edit later. It is quite difficult to capture the child's face but We need to see general movement of the facial muscles**

*****Click on the video to play**



Step 1: Select the corresponding numbered study medication kit.

Step 2: Determine the patient's dose of BelliC Study Drug (prednisolone/placebo):

Weight	Volume of BelliC Study Drug 5mg/mL (mL)	Dose (mg)
5 kg to <7.5 kg	1.5 mL	(7.5 mg)
7.5 kg to <10 kg	2 mL	(10 mg)
10 kg to <15 kg	3 mL	(15 mg)
15 kg to <20 kg	4 mL	(20 mg)
20 kg to <25 kg	5 mL	(25 mg)
25 kg to <30 kg	6 mL	(30 mg)
30 kg to <35 kg	7 mL	(35 mg)
35 kg to <40 kg	8 mL	(40 mg)
40 kg to <45 kg	9 mL	(45 mg)
45 kg or greater	10 mL	(50 mg)

Step 3: Complete script below:

CLINICAL TRIAL PRESCRIPTION
BelliC Study HREC/15/RCHM/V4

Attach *Bradma* Here

PREDNISOLONE 5mg/mL OR PLACEBO ORAL SOLUTION

Give mL by measure ONCE daily in the morning with food for 10 DAYS as directed.

Supply: 2 or 4 bottles (circle) x 30 mL Kit#:

Dr (NAME):

Dr (SIGN): Date: / /

The doctor must fill out this script (for legal reasons), this replaces the pharmacy script

Step 4: Select correct amount of bottles to supply.

Complete label of EACH bottle to be supplied including DOSE and patient details

Weight	Bottles to Supply	Bottles to Place in 'Return to Pharmacy' Box
5 kg to <25 kg	2 BOTTLES	RETURN 2 BOTTLES TO THE PHARMACY BOX
≥ 25 kg	4 BOTTLES	N/A

The patient needs 10 day supply, therefore

- Between 5kg to <25kg they need 2 bottles
- Over 25kg they need 4 bottles

Step 5: Administer the first dose of the study medication:

Sign _____ Date: ___/___/___ Time: ___/___/___

Step 6: Provide the patient with the study medication.

Step 7: Complete page 3 of the Study Participant Card, indicating when the patient should take Dose 2. Provide this to the patient

First Dose Given	Second Dose To Be Given
Before midnight	The next morning
After midnight	The morning of the following day

The RN/Dr who administers the dose should sign here to replace hospital medication chart

Study Participant card

This will be printed on card paper and folded over

It has all the instructions for the study on it and should remain with the participant/parent at all times

<p>If your child vomits within 30 minutes of the medicine, please repeat dose.</p> <p>Paracetamol, Ibuprofen, Antihistamines and Antibiotics can be used in combination with Prednisolone.</p> <p>Avoid live vaccines for 6 weeks after finishing the study medication.</p> <p style="text-align: right;">4</p>	<p style="text-align: center;"><i>Royal Children's Hospital & MCRI</i></p> <h2 style="text-align: center;">Study Participant Card</h2> <h3 style="text-align: center;">Bell's Palsy in Children (BellPIC)</h3> <p style="text-align: center;">HREC/15/RCHM/V4</p> <p>Bell's Palsy in children: a multi-centre, randomized blinded, placebo controlled trial to determine whether prednisolone improves time to recovery at 1 month.</p> <p style="text-align: right;">1</p>																						
<p style="text-align: center;">This participant is receiving the following: Prednisolone (1mg/kg) or matching placebo for 10 days.</p> <p>Any study related questions/concerns please contact: <i>Study Coordinator: Amanda Williams</i> 99366635 <i>amanda.williams@rch.org.au</i></p> <p style="text-align: right;">2</p>	<p>Please tick off each day that your child receives their medication.</p> <p>The next dose is due in the morning on ___/___/___</p> <p style="text-align: center;">↓</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="padding: 5px;">DAY</th> <th style="padding: 5px;">1</th> <th style="padding: 5px;">2</th> <th style="padding: 5px;">3</th> <th style="padding: 5px;">4</th> <th style="padding: 5px;">5</th> <th style="padding: 5px;">6</th> <th style="padding: 5px;">7</th> <th style="padding: 5px;">8</th> <th style="padding: 5px;">9</th> <th style="padding: 5px;">10</th> </tr> </thead> <tbody> <tr> <td style="padding: 5px;">DOSE GIVEN (✓)</td> <td style="text-align: center; padding: 5px;">✓</td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> </tr> </tbody> </table> <p><i>Do not throw out the bottles</i>, please bring with you to your first appointment with the study team.</p> <p style="text-align: right;">3</p>	DAY	1	2	3	4	5	6	7	8	9	10	DOSE GIVEN (✓)	✓									
DAY	1	2	3	4	5	6	7	8	9	10													
DOSE GIVEN (✓)	✓																						

EYE CARE FOR BELL'S PALSY PATIENTS

Sometimes when a child has Bell's palsy it becomes difficult to close the affected eye. It is important that they have lubricating eye drops prescribed and that you use them often (several times per day).

After discussion with the ophthalmology service at The Royal Children's Hospital in Melbourne our advice is as follows:

DAY CARE: Apply Celluvisc drops 2-3 hourly throughout the day to the affected eye.

NIGHT CARE: Apply Gentel drops/gel in the evening before bed. For older children if the affected eye is not closing then it may be taped closed using paper tape at bedtime. Taping of the eyelid closed is usually tolerated well amongst older children but is not a necessity, so not advised with younger children and infants as it is likely to just cause distress.

Both of these medications are available over the counter at most pharmacies.

Please don't hesitate to contact us if you have any further enquiries.

What happens next?

For the patient:

- Once they have been administered the first dose of study drug, the patient can be discharged
- The study team will call them in 10-14 days to assess drug compliance, adverse events and recovery
- The patient will then return for a follow up visit at one month post randomisation
 - This will either be with a neurologist/specialist paediatrician/emergency consultant

BellPIC

Bell's Palsy in Children Study

Follow Up

Bell's palsy in Children (BellPIC)

Time Points

- Emergency:
 - CRF 1- Eligibility Criteria
 - CRF 2- Randomisation Form
- As soon as possible following ED presentation:
 - CRF 3- Pt details & History of Presenting Illness
 - CRF 4- ED Assessment
- 10 -14 days after ED presentation
 - Follow up phone call
- 1 Month after ED presentation
 - Follow up visit

Immediately following ED presentation

In Emergency:

- Collect CRF 1 & CRF 2 from Emergency
- Complete dispensing log
- Ensure Patient Identification Sheet has been filled in
- Check study medications

In the Office:

- Complete log book
- Enter CRF 1 & CRF 2 into RedCap database
- Upload photos/videos from ipod into database
- Also save onto secure hard drive as back up
- Delete photos from ipad and return to ED

Dispensing Log

CLINICAL TRIAL

Bell's Palsy in Children Study ([BellPIC](#))

DISPENSING LOG

Site Name: _____ Site Prefix: _____ Investigator: _____ Page ____ of ____

STUDY MEDICATION KITS*

*Each kit contains:

Bell Pic Study Drug (Prednisolone 5 mg/mL or Placebo) Oral Solution 4 x 30mL bottles, 2 x 10mL oral syringes, 2 x 3mL oral syringes and a Study Participant Card

DATE	STOCK Study Coordinator: Re-order stock when Number of Kits on Hand = 2			DISPENSING Refer to Dispensing Procedure				SIGN
	Number of Kits Received (+) or Dispensed (-)	Batch and Expiry	Number of Kits On Hand (Balance)	Patient Initials	Study Number	Number of Bottles Supplied Tick (✓)	Number of Bottles Returned Tick (✓)	
01/JAN/15	+ 4	ZZ11/AA22 31/DEC/15	4	-	-	<input type="checkbox"/> 2 <input type="checkbox"/> 4	<input type="checkbox"/> 2 <input type="checkbox"/> 0	AB
03/JAN/15	- 1	ZZ11/AA22 31/DEC/15	3	AZ	ABC-001	<input checked="" type="checkbox"/> 2 <input type="checkbox"/> 4	<input checked="" type="checkbox"/> 2 <input type="checkbox"/> 0	Dr. CD
						<input type="checkbox"/> 2 <input type="checkbox"/> 4	<input type="checkbox"/> 2 <input type="checkbox"/> 0	
						<input type="checkbox"/> 2 <input type="checkbox"/> 4	<input type="checkbox"/> 2 <input type="checkbox"/> 0	
						<input type="checkbox"/> 2 <input type="checkbox"/> 4	<input type="checkbox"/> 2 <input type="checkbox"/> 0	
						<input type="checkbox"/> 2 <input type="checkbox"/> 4	<input type="checkbox"/> 2 <input type="checkbox"/> 0	
						<input type="checkbox"/> 2 <input type="checkbox"/> 4	<input type="checkbox"/> 2 <input type="checkbox"/> 0	

DO NOT FILE THIS SHEET – RETURN TO RESEARCH BOX



CLINICAL TRIAL Bell's Palsy in Children Study (BellPIC)

PATIENT IDENTIFICATION SHEET

Site Name: _____ Site Prefix: _____ Investigator: _____ Contact Number: _____

Patient Name and UR Number (Attach Patient Label Sticker)	Study Number (see Medication Kit)	Dr Sign	Date

DO NOT FILE THIS SHEET- RETURN TO RESEARCH BOX

CRF 3: Pt details and History of Presenting Illness

- Will be entered directly into RedCAP by RA
- Information will be collected from
 - EDIS (HAS)
 - Patients medical record
- Any unknown information
 - Write on page for follow up
 - Ask parents in follow up phone call
- Paper copy of CRF available
 - To be used until RedCAP up and running
- Treating doctor
 - How difficult they found HB and Sunnybrook

CRF 4: ED Assessment

- Will be entered directly into RedCAP by RA
- Information will be collected from
 - EDIS (HAS)
 - Patients medical record
- Any unknown information
 - Write on page for follow up
 - Ask parents in follow up phone call
- Paper copy of CRF available
 - To be used until RedCAP up and running
- Questions relating to treatment in ED
 - Date and time seen, triage category, admission, discharge
 - Tests conducted, Specialty reviews

BellPIC: Bell's Palsy in Children Study

Study Number: RCHM

Study Checklist:

- CRF 1**
- CRF 2**
- CRF 3**
- CRF 4**
- CRF 5**
10-14 day follow up due: ___ / ___ / ___
- CRF 6**
1 month follow up due: ___ / ___ / ___
Booked: ___ / ___ / ___ ___ : ___
 - Reminder text/email sent
 - Car park pass ordered
- 3 month follow up due: ___ / ___ / ___**
 - Survey
 - Follow up visit
Booked: ___ / ___ / ___ ___ : ___
- 6 month follow up due: ___ / ___ / ___**
 - Survey
 - Follow up visit
Booked: ___ / ___ / ___ ___ : ___
- Redcap data entry**

Keeping track of Time Points

- Once patient is entered into RedCAP, the program will automatically generate dates in the calendar
- We have also created a tick list to put in the front of the patient's file:

CRF 5: Follow up phone call

- Completed 10-14 days post ED presentation
- Main aims
 - Assess drug compliance
 - Assess recovery
 - Adverse events
- Ensure patients do not throw out study drug
- Organize appointment for 1 month follow up
- Ask any questions that were unknown on previous CRF's

CRF 6: One Month Follow Up Visit

- Face to face meeting with participant
- Neurologist/ Emergency Consultant/ Specialist Paediatrician
- Research Nurse
- Different versions for different ages
 - 6-24 months
 - 2-3 years
 - 4 years old
 - 5-7 years
 - 8-12 years
 - 13-18 years
 - All have parent proxy versions if children are unable to complete

Timing of One Month Visit:

- Minimum of 28 days post randomisation, up to 35 days.
- *In extreme circumstances, visits can be arranged between 21-28 days if patients are unable to attend post 28 days.*

CRF 6: One Month Follow Up Visit

Preparation

- Organise room booking
- Double check clinician is available
- Ensure you have ipod for photos/videos
- Arrange car parking passes

BELLPIC
Bell's Palsy in Children Study

Study Number: RCHM

CRF 6 : ONE MONTH FOLLOW UP 8-12 YEARS

6.1 Research Nurse: _____
 6.2 Specialist Clinician: _____
 6.3 Date: / / (dd/mm/yyyy)
 6.4 Please collect the study drugs from the family.
 Yes No, reason why not _____
 *Study drugs must be returned to pharmacy to be measured and disposed of.
 6.5 Ethnicity:
 Caucasian Aboriginal/Torres Strait Islander Maori
 Pacific Islander (Specify) _____ Middle Eastern or Arabic
 Asian African (specify) _____ Other (specify) _____

Patient/parent perception:

6.6 Does the patient feel that the symptoms of Bell's Palsy have resolved completely?
 Yes No Unknown
 6.7 Date of resolution (as per parent/patient):
 / (dd/mm/yyyy) Unknown date (but between phone call & now)
 6.8 Does the patient report any abnormal hearing (hyperacusis, tinnitus) since onset of symptoms
 Yes No, skip to qn. 6.9 Unknown
 6.8.1 If yes, does the abnormal hearing continue
 Yes No Unknown
 6.8.2 If resolved, how long did it last for _____
 6.9 Does the patient report any reduced or increased tear production since onset of symptoms
 Yes No, skip to qn 6.10 Unknown
 6.9.1 If yes, which one
 Reduced tear production Increased tear production Unknown
 6.9.2 Does it continue? _____

Yes No Unknown

6.9.2 If resolved, how long did it last for _____

6.10 Does the patient report any altered taste since onset of symptoms
 Yes No, skip to qn 6.11 Unknown

6.10.1 If yes, does the altered taste continue
 Yes No Unknown

6.10.2 If resolved, how long did it last for _____

6.11 Over the past month, has the patient had any days off from school/day care due to Bell's Palsy?
 Yes No Unknown

6.11.1 If yes, please specify how many days _____

6.11.2 Who cared for the child during these days?

Parent, time off work

Parent, no time off work required

Unpaid informal carer

Paid carer, specify how much this costs (per day) _____

If paid carer, did they receive the child care benefit:

Yes No Unknown

No care required (older children)

6.12 Has there been any inpatient, outpatient or ED visits to the study site or other health service or GP during the study period due to the Bell's Palsy (other than scheduled study visits)

Yes No, skip to qn 6.13 Unknown

6.12.1 If yes, where did the patient visit: (tick all that apply)

GP

Emergency Department

Outpatient visit

Hospital admission

Other health service, describe _____

6.12.2 Please specify how many times they used each service _____

Page 1-3 the same for all ages

Collect study drugs and return to pharmacy

Ages listed here



6.13 Did you seek any alternative therapies, [eg, acupuncture](#), naturopath, [etc](#)?

Yes No, [skip to qn 6.14](#) Unknown

6.13.1 If yes, please specify _____

6.14 Was there a reaction to the study drug? **In the last 2 weeks since the phone call*

Yes No, [skip to qn 6.15](#) Unknown

6.14.1 If yes, please specify

Fatigue

Insomnia

Increased appetite

Polyuria

Rash

Other _____

6.14.2 Do these symptoms continue or have they resolved?

Continue Resolved

6.15 Were any tests, such as blood tests or neuroimaging, conducted since the phone call (2 weeks ago)?

Yes No, [skip to qn 6.16](#) Unknown

6.15.1 If yes, which tests were conducted?

Blood tests

Head CT

Head MRI

Lumbar puncture

Other _____

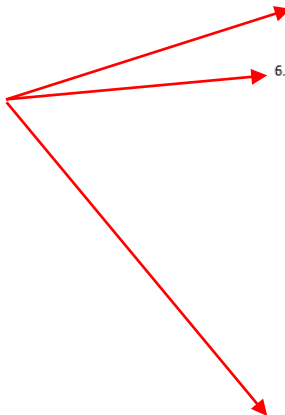
Unknown

6.15.2 If yes, please outline results _____

6.16 For the clinician: On your assessment is there any indication for an alternative diagnosis (other than [Bell's Palsy](#))?

No Yes, Specify: _____

New Questions



TO BE COMPLETED BY THE CLINICIAN

Step 2: CLINICIAN ASSESSMENTS

The following assessments are to be carried out by the clinician and the research nurse. The research nurse can *assist* the clinician to undertake the scoring of the facial palsy and synkinesis. However, *the scoring decision will be as per the clinician.*

Facial Grading Scales

Please circle the grade you believe to be most applicable to the patient

6.12 Modified HB scale

GRADE	DEFINITION
I	Normal symmetrical function in all areas
II	Slight weakness noticeable only on close inspection. Complete eye closure with minimal effort. Slight asymmetry of smile with maximal effort. <u>Synkinesis</u> barely noticeable; contracture or spasm absent
III	Obvious weakness, but not disfiguring. May not be able to lift eyebrow. Complete eye closure; strong but asymmetrical mouth movement with maximal effort. Obvious, but not disfiguring <u>synkinesis</u> , mass movement or spasm
IV	Obvious disfiguring weakness. Inability to lift brow. Incomplete eye closure and asymmetry of mouth with maximal effort. Severe <u>synkinesis</u> , mass movement, spasm
V	Motion barely perceptible. Incomplete eye closure, slight movement of corner of mouth. <u>Synkinesis</u> , contracture and spasm usually absent
VI	No movement; loss of tone; no <u>synkinesis</u> , contracture or spasm

To be completed by the
clinician

Primary Outcome





6.13 **Sunnybrook Facial Grading System:**

Please circle/tick the appropriate boxes and numbers. You can calculate the score once the patient has left.

To be completed by the clinician

Sunnybrook Facial Grading System		
Resting Symmetry	Symmetry of Voluntary Movement	Synkinesis
Compared to normal side	Degree of muscle EXCURSION compared to normal side	Rate the degree of INVOLUNTARY MUSCLE CONTRACTION associated with each expression
Eye (choose one only) normal 0 narrow 1 wide 1 eyelid surgery 1 Cheek (naso-labial fold) normal 0 absent 2 less pronounced 1 more pronounced 1 Mouth normal 0 corner drooped 1 corner pulled up/out 1 Total <input type="checkbox"/>	Standard Expressions Forehead Winkle (FRD) 1 2 3 4 5 <input type="checkbox"/> Gentle eye closure (DCS) 1 2 3 4 5 <input type="checkbox"/> Open mouth smile (ZYG/RIS) 1 2 3 4 5 <input type="checkbox"/> Snarl (LLA/LLS) 1 2 3 4 5 <input type="checkbox"/> Lip Pucker (OOD/OOI) 1 2 3 4 5 <input type="checkbox"/> Total <input type="checkbox"/>	NONE: No synkinesis or other movement MILD: Slight tightness MODERATE: Distorts but not distorting analysis SEVERE: Distorting synkinesis/ Gross motor movement of several muscles Total <input type="checkbox"/>
Resting symmetry score Total X 5 <input type="checkbox"/>	Voluntary movement score: Total X 4 <input type="checkbox"/>	Synkinesis score: Total <input type="checkbox"/>
Patient's name _____ Dx _____ Date _____	Vol mov't score <input type="checkbox"/> - Resting symmetry score <input type="checkbox"/> - Synk score <input type="checkbox"/> = Composite score <input type="checkbox"/>	

Scores can be added after visit by Research Nurse

To be completed by
the clinician in
conjunction with the
parent/participant

6.14 Synkinesis Assessment Questionnaire (SAQ):

Please talk the parent through the synkinesis questionnaire. Answer the following questions, on a scale from 1-5, according to the following scale:

- 1 = seldom or not at all
- 2 = occasionally, or very mildly
- 3 = sometimes, or mildly
- 4 = most of the time, or moderately
- 5 = all the time, or severely

	Question	Score (1-5)
I	When I smile, my eye closes	
II	When I speak, my eye closes	
III	When I whistle or pucker my lips, my eye closes	
IV	When I smile, my neck tightens	
V	When I close my eyes, my face gets tight	
VI	When I close my eyes, the corner of my mouth moves	
VII	When I close my eyes, my neck tightens	
VIII	When I eat, my eye waters	
IX	When I move my face, my chin develops a dimpled area	
Sum of Scores I - IX		
**SAQ Total Score		

**SAQ Total Score = Sum of scores for questions 1-9/ 45 x 100

To be completed by
the Research Nurse

Photos and videos to
be taken again
Uploaded into RedCap
following visit

TO BE COMPLETED BY THE RESEARCH NURSE

Facial Photos or Videos

Step 1: Please get the [BellPIC tool](#) out of the study box. Swipe open and open the camera

Children old enough to follow commands:

We require both photographs and videos

Photos:

We require 4 poses:

- At rest (eyes open, no expression)
 - Smiling
 - Eyes closed tightly, clenched
 - Raised eyebrows
- (Note: all of poses 2-4 are highly exaggerated, 'forced')*

Please follow the below examples:



Videos:

Please ask the child to perform all 4 poses again and film the child's face whilst they complete them

Children not able to follow commands:

Videos

Please take a video of the child's face- we need to be able to see the level of facial palsy. The video should include the child actively trying to move their face [ie. opening](#) mouth, closing eyes, crying or smiling.

Please take as many videos as you feel necessary to capture facial movement.

Step 2: Once the study visit is complete, please upload the photos directly into [RedCap](#) (see "RA manual" for further instructions on uploading into [RedCap](#))

TO BE COMPLETED BY THE PATIENT/PARENT WITH ASSISTANCE BY RESEARCH NURSE

Step 3: PATIENT / PARENT ASSESSMENT

The following assessments are to be carried out by the *patient and/or parent*, depending on the questionnaire.

- **PedsQL**: The patient should be able to complete this, however there is a parent version available as well
- **CHU9D**: Parents to complete this questionnaire
- **Harter Physical Appearance scale**: Pictorial questionnaire for the child to fill out, age dependant

Please *assist* the patient/parent in understanding how to fill out each of the questionnaires by going through *each* questionnaire with *them*.

Allow the patient time to answer the questionnaires *independently* but be present to answer any questions that may arise.

Follow the directions in each of the boxes that explain how to carry out the questionnaires. Refer to the "Instructions for RA's" manual for further directions

To be completed by
the Research Nurse in
conjunction with the
parent/participant

6.18 House Brackmann- Parent Perception.

Please provide the parent/patient with the *House Brackmann Lay form* and ask the parent to choose which grade of facial severity they believe their child is (*tick one only*)

1 2 3 4 5 6

6.19 Pain scale

Please instruct the patient and parent to circle the appropriate number to reflect their pain score.

6.19.1 *Child:*



6.19.2 *Parent:*



Participants to use
VAS/Faces age
dependant

Parents to use VAS

Questionnaires

The questionnaires are all *age dependent*.

*Younger ages do not have some questionnaires

Instructions on how to complete questionnaires will all be found in the CRF 6 separate to questionnaire

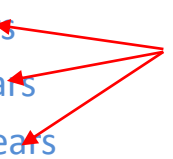
*talk parent/participant through instructions but allow them to fill in questionnaire independently

Questionnaires include:

- Quality of Life
 - PedsQL
 - CHU9D
- Harter Appearance Scale

Quality of Life: PedsQL

PedsQL is divided into the following age groups:

- 2-4 years (Parents to fill out)
 - 5-7 years
 - 8-12 years
 - 13-18 years
- (Participants to fill out)
- 

*** There are parent proxy versions for all these age groups as well if children are unable to fill them in

6.18 PedsQL: Paediatric Quality of Life Inventory

An example of the
instructions

PATIENT TO FILL OUT

INSTRUCTIONS TO READ OUT FOR THE PATIENT

I am going to ask you some questions about things that might be a problem for some children. I want to know how much of a problem any of these things might be for you.




(Show the child the template and point to the responses as you read)

If it is never a problem for you, point to the smiling face

It is sometimes a problem for you, point to the middle face

If it is almost always a problem for you, point to the frowning face

I will read each question. Point to the pictures to show me how much of a problem it is for you. Let's try a practice one first.

	Never	Some- times	Almost always
Is it hard for you to click your fingers			

An example of the
questionnaire
(5-7 years)

In the **LAST MONTH**, how much of a **problem** has this been for you...

PHYSICAL FUNCTIONING (problems with...)	Never	Some-times	Almost always
1. Is it hard for you to walk?	0	2	4
2. It is hard for you to run?	0	2	4
3. It is hard for you to play sport or do exercise?	0	2	4
4. It is hard for you to pick up big things?	0	2	4
5. It is hard for you to have a bath or shower?	0	2	4
6. It is hard for you to help around the house (like pick up your toys?)	0	2	4
7. Do you get aches and pains? (Where?.....)	0	2	4
8. Do you ever feel too tired to play?	0	2	4

EMOTIONAL FUNCTIONING (problems with...)	Never	Some-times	Almost always
1. Do you feel scared?	0	2	4
2. Do you feel sad?	0	2	4
3. Do you feel angry?	0	2	4
4. Do you have trouble sleeping	0	2	4
5. Do you worry about what will happen to me	0	2	4

SOCIAL FUNCTIONING (problems with...)	Never	Some-times	Almost always
1. Is it hard for you to get along with other kids?	0	2	4
2. Do other kids say they do not want to play with you?	0	2	4
3. Do other kids tease you?	0	2	4
4. Can other kids your age do things that you cannot do?	0	2	4
5. It is hard for you to keep up when you play with other kids?	0	2	4

SCHOOL/PRESCHOOL FUNCTIONING (problems with...)	Never	Some-times	Almost always
1. It is hard for you to pay attention at school/preschool?	0	2	4
2. Do you forget things?	0	2	4
3. Is it hard to keep up with work at school/preschool?	0	2	4
4. Are you away from school/preschool because you feel sick?	0	2	4
5. Are you away from school/preschool because you have to go to the doctor or hospital?	0	2	4

Only circle one option
per line

Quality of Life: CHU9D

CHU9D is divided into the following age groups:

- 5-7 Parent Proxy
- 8-18 to be filled in by the participant
- There are no CHU9D questionnaires before 5 years of age

*** CHU9D is a new QOL scale that also collects health economic data

The explanations

6.19 CHU9D: Child Health Utility 9D

PARENTS TO FILL OUT

INSTRUCTIONS TO READ OUT FOR THE PATIENT

These questions ask about how your child is **today**. For each question, read all the choices and decide which one is most like your child **today**.

The questions are general questions, not just about Bell's Palsy. About your child's general life.

Then put a tick in the box next to it like this . Only tick one box for each question

Example:

Today my child feels quite upset so I will tick this box:

Upset

- I don't feel upset today
- I feel a little bit upset today
- I feel a bit upset today
- I feel quite upset today
- I feel very upset today

Now think about and answer the rest of the questions below

6.19 CHU9D: Child Health Utility 9D

DIRECTIONS

These questions ask about how you are today. For each question, read all the choices and decide which one is most like you today.

Then put a tick in the box next to it like this . Only tick one box for each question

Example:

Today I feel quite upset so I will tick this box:

Upset

- I don't feel upset today
- I feel a little bit upset today
- I feel a bit upset today
- I feel quite upset today
- I feel very upset today

Now think about and answer the rest of the questions below

9 questions in total

Tick one answer per
question

1. Worried

- I don't feel upset today
- I feel a little bit upset today
- I feel a bit upset today
- I feel quite upset today
- I feel very upset today

2. Sad

- I don't feel sad today
- I feel a little bit sad today
- I feel a bit sad today
- I feel quite sad today
- I feel very sad today

3. Pain

- I don't have any pain today
- I have a little bit of pain today
- I have a bit of pain today
- I have quite a lot of pain today
- I have a lot of pain today

4. Tired

- I don't feel tired today
- I feel a little bit tired today
- I feel a bit tired today
- I feel quite tired today
- I feel very tired today

5. Annoyed

- I don't feel annoyed today
- I feel a little bit annoyed today
- I feel a bit annoyed today
- I feel quite annoyed today
- I feel very annoyed today

6. School Work/ Homework (such as reading, writing, doing lessons)

- I have no problems with my schoolwork/homework today
- I have a few problems with my schoolwork/homework today
- I have some problems with my schoolwork/homework today
- I have many problems with my schoolwork/homework today
- I can't do my schoolwork/homework today

7. Sleep

- Last night I had no problems sleeping
- Last night I had a few problems sleeping
- Last night I had some problems sleeping
- Last night I had many problems sleeping
- Last night I had couldn't sleep at all

8. Daily routine (things like eating, having a bath/shower, getting dressed)

- I have no problems with my daily routine today
- I have a few problems with my daily routine today
- I have some problems with my daily routine today
- I have many problems with my daily routine today
- I can't do my daily routine today

9. Able to join in activities (things like playing out with your friends, doing sports, joining in things)

- I can join in with any activities today
- I can join in with most activities today
- I can join in with some activities today
- I can join in with a few activities today
- I can join in with no activities today

Harter Appearance Scale

Harter is divided into the following age groups:

- Harter Pictorial: Ages 4-7
 - Divided further:*
 - 4-5 Boys & girls
 - 5-7 Boys & girls
- Harter Children: 8-12
- Harter Adolescent: 13-18

* No scales for younger than 4 years old

Harter Pictorial Scale

4 different scales:

- 4-5 boys
- 4-5 girls
- 6-7 girls
- 6-7 boys

The recording and scoring sheets are divided into age groups:

4-5 years old

6-7 years old

This can be calculated at a later time

6.20 Harter Appearance Scale

Instructions for the research nurse

PATIENT TO FILL OUT

Harter Pictorial

The Harter Pictorial Appearance Scale is broken up into 4 different components according to age.

1. Girls aged 4-5
2. Boys aged 4-5
3. Girls aged 6-7
4. Boys aged 6-7

Please choose the appropriate Pictorial Scale. You will find further instructions on these scales.

Also please choose the appropriate Recording and Scoring Sheet

1. Ages 4-5 (both boys and girls)
2. Ages 6-7 (both boys and girls)

Simply place the score (found inside the circle- will be 1-4) in the appropriate box.

Add the scored together for the overall total.

Then divide the scores by 6 to work out the mean.

Use the following script to explain the Harter Scale to the child

The child is given a sample item at the beginning and instructed as follows:

I have something here that's kind of like a picture game and its called WHICH BOY IS THE MOST LIKE ME. I'm going to tell you about what each of the boys in the picture is doing.

Sample: In *this* one (examiner then points to picture on the left), this boy is usually kind of *happy*, and this boy (examiner points to the picture on the right) is usually kind of *sad*. Now, I want you to tell me which one of these boys is the most like you.

After the child has pointed to the picture appropriate for her, the examiner points to the circles directly below the picture that emphasizes the key qualifying words to help the child refine her choice further. The examiner should always start with the extreme (larger) circle and proceed to the smaller circle. Thus, if the child points to the happy picture in response to the question concerning which is most like him, the examiner would say:

Are you *always* happy? (pointing to the larger circle)

Or are you *usually* happy (pointing to the smaller circle)

Occasionally a child will point to the middle of the two pictures and say they are both like her. The examiner should then say: Yes, sometimes we do feel both ways, but if you had to pick, which one of these boys is the way you are *most* of the time, which one would you choose?

The number value corresponding to the child's choice should be recorded on the Scoring Sheet for Individual Child Responses. Any comments should be recorded in the space provided at the bottom of the sheet.

The examiner continues for each plate, reading the descriptions, verbatim, as she/he points to the picture accompanying each description. In some pictures, there is a target child central to the description, designated by an arrow pointing to that child. Be certain that on these items you point to that particular child.

Instructions for
the patient

The research nurse is to read out the question to the child while pointing to the appropriate picture

The child then chooses which picture is most like them

Then they choose if it is A LOT like them, or just A LITTLE bit like them

The number used to score is in the circle on the RA page

The child should only see the picture page, not the question

This will be on a hard page/laminated spiral book

SAMPLE QUESTION

This boy is usually kind of happy. Are you:

This boy is usually kind of sad. Are you:

Always happy

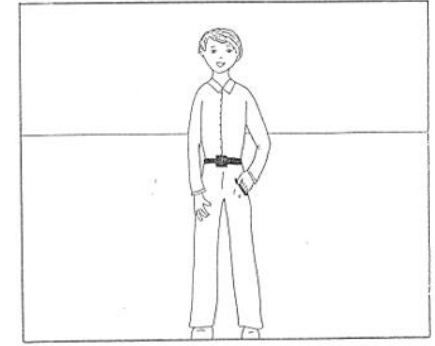
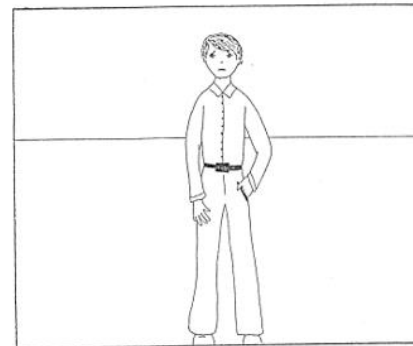
OR

Usually happy

Usually sad

OR

Always sad





Sample sentence

A	Really true for me <input type="checkbox"/>	Sort of true for me <input type="checkbox"/>	Some kids would rather play outdoors in their spare time	BUT	Other kids would rather watch TV	Sort of true for me <input type="checkbox"/>	Really true for me <input type="checkbox"/>
---	--	---	--	-----	-------------------------------------	---	--

1	Really true for me <input type="checkbox"/>	Sort of true for me <input type="checkbox"/>	Some kids are happy with the way they look	BUT	Other kids are not happy with the way they look	Sort of true for me <input type="checkbox"/>	Really true for me <input type="checkbox"/>
---	--	---	---	-----	---	---	--

2	Really true for me <input type="checkbox"/>	Sort of true for me <input type="checkbox"/>	Some kids are happy with their height and weight	BUT	Other kids wish their height or weight were different	Sort of true for me <input type="checkbox"/>	Really true for me <input type="checkbox"/>
---	--	---	--	-----	---	---	--

3	Really true for me <input type="checkbox"/>	Sort of true for me <input type="checkbox"/>	Some kids wish their body was different	BUT	Other kids like their body the way it is	Sort of true for me <input type="checkbox"/>	Really true for me <input type="checkbox"/>
---	--	---	--	-----	---	---	--

4	Really true for me <input type="checkbox"/>	Sort of true for me <input type="checkbox"/>	Some kids wish their physical appearance (how they look) was different	BUT	Other kids like their physical appearance the way it is	Sort of true for me <input type="checkbox"/>	Really true for me <input type="checkbox"/>
---	--	---	---	-----	---	---	--

Children scale

Harter Appearance Scale

Adolescent scale

	Really True for me	Sort of True for me		BUT		Sort of True for me	Really True for me
Sample Sentence							
a.	<input type="checkbox"/>	<input type="checkbox"/>	Some teenagers like to go to movies in their spare time	BUT	Other teenagers would rather go to sports events	<input type="checkbox"/>	<input type="checkbox"/>
1.	<input type="checkbox"/>	<input type="checkbox"/>	Some teenagers are <i>not</i> happy with the way they look	BUT	Other teenagers are happy with the way they look	<input type="checkbox"/>	<input type="checkbox"/>
2.	<input type="checkbox"/>	<input type="checkbox"/>	Some teenagers wish their body was different	BUT	Other teenagers like their body the way it is	<input type="checkbox"/>	<input type="checkbox"/>
3.	<input type="checkbox"/>	<input type="checkbox"/>	Some teenagers wish their physical appearance was different	BUT	Other teenagers like their physical appearance the way it is	<input type="checkbox"/>	<input type="checkbox"/>
4.	<input type="checkbox"/>	<input type="checkbox"/>	Some teenagers think that they are good looking	BUT	Other teenagers think that they are not very good looking	<input type="checkbox"/>	<input type="checkbox"/>
5.	<input type="checkbox"/>	<input type="checkbox"/>	Some teenagers really like their looks	BUT	Other teenagers wish they looked different	<input type="checkbox"/>	<input type="checkbox"/>

CRF 6 is now complete

Thank the family for coming in to the 1 month follow up
Provide family with a car park pass if applicable

For those recovered (HB=1)

- Questionnaires will be sent out in the mail at 3 & 6 months

For those not recovered (HB 2-6)

- They will need to return for a 3 month follow up visit

Ensure that if needed, the patient has been referred to an appropriate specialist

Following the One Month Visit (Primary Outcome)

The involvement of the participant following the one month visit is entirely dependent on their recovery from the Bell's Palsy

They are divided into two groups:

- Recovered (HB=1)
- Not recovered (HB 2-6)

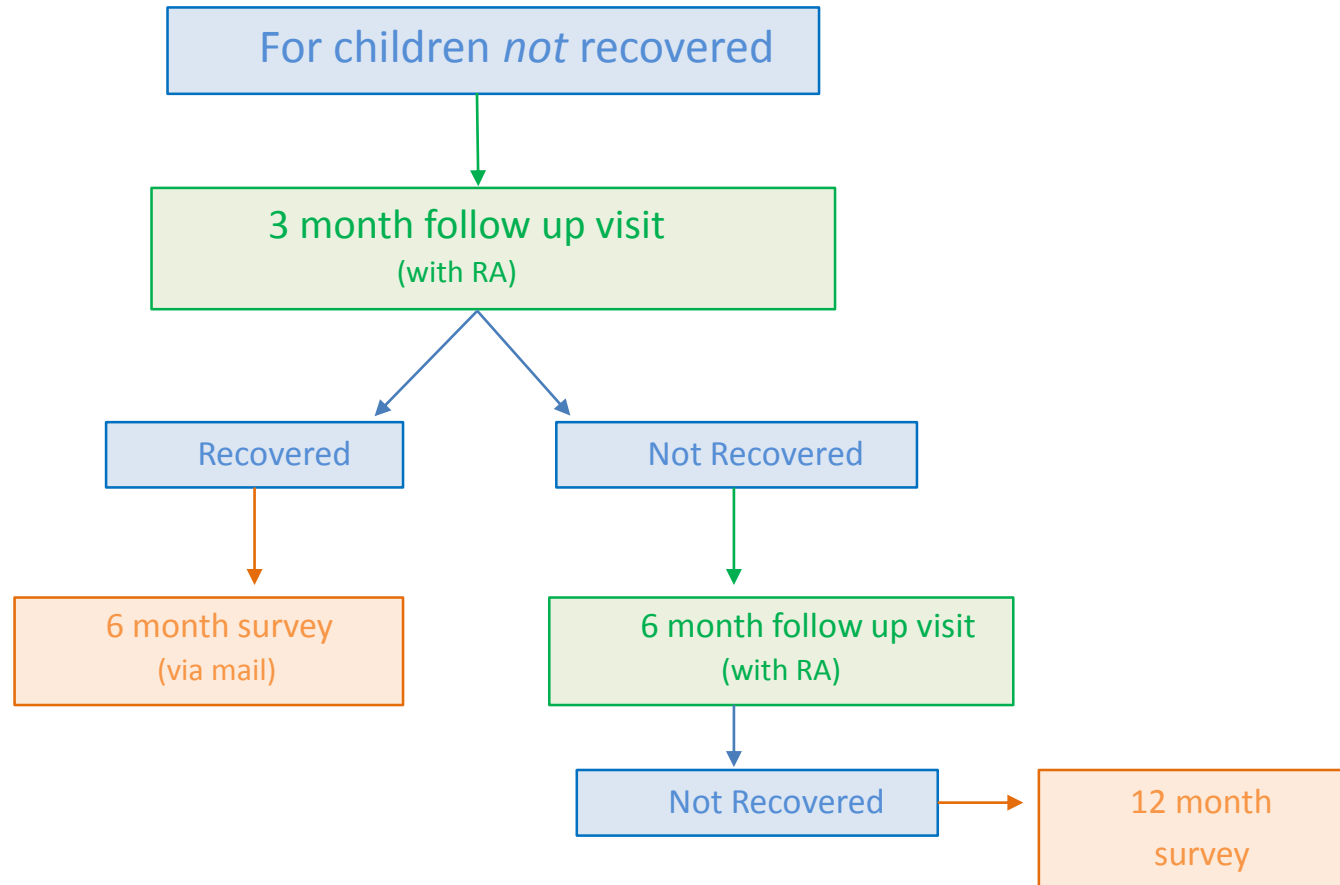
Time Points: *Recovered*

For children recovered at one month



3 & 6 month survey
(via mail and phone)

Time Points: *Not Recovered*



3 Month Follow Up: *Non-Recovered*

Non recovered will come in for a Study Visit at 3 months

- With the Research Nurse +/- Clinician

CRF 7 to be completed

- Identical to CRF 6
- Asks all the same questions
- Same questionnaires
- Photos and videos

3 Month Follow Up: *Recovered*

Non recovered are required to complete a survey sent to them in the mail

Comprises of two parts:

1. Send age appropriate survey to families

- Contains cover letter, pain scale, HB Lay, PedsQL, CHU9D & Harter Appearance Scale
- The letter will instruct the families to complete the surveys in preparation for phone call

2. Call the families

- Aim is to see if symptoms have returned or gotten worse, assess HB Lay
- If symptoms have returned, we ask further questions, ie. Hearing, lacrimation, altered taste, health economics questions etc
- If still remain recovered, will go straight to questionnaires

**Entered directly into RedCAP database- CRF 7



The Royal Children's Hospital Melbourne
50 Flemington Road
Parkville Victoria 3052 Australia
TELEPHONE +61 3 9345 5522
www.rch.org.au

<Date>

<Parents Name>

<Address>

|

Dear <Parents names>,

RE: <Participant Name>

Thank you for continuing to be a part of the [BellPIC Study](#) ([Bell's Palsy](#) in Children)

We would like to ask some more questions about <participants name's> recovery from the [Bell's Palsy](#) that <he/she> was diagnosed with three months ago.

We have attached a series of questionnaires similar to those that yourselves and <participant> filled in when <he/she> presented to the hospital for her one month follow up.

We would love for you and <participant> to answer these questions again in order to see any ongoing effects of the [Bell's Palsy](#) even after recovery.

The research team will phone you within the next week to discuss the surveys, ask a few further questions about <participant>'s recovery and answer any questions that you may have. If you could complete the surveys prior to the phone call it would be greatly appreciated.

Once again, thank you so much for taking part in our research project.

Sincerely

<Ms Amanda Williams>

Research Coordinator

Emergency Department

The Royal Children's Hospital

50 Flemington Road

Parkville Victoria 3052

Telephone (03) 9936 6635

Email Amanda.williams@rch.org.au

BELLPIC Bell's Palsy in Children Study

Study Number: RCHM

THREE MONTH SURVEY

INSTRUCTIONS FOR THE RESEARCHER

The three month survey is for participants who were FULLY RECOVERED (ie. HB=1) at their one month visit.

Prior to this phone call, ensure participant has received survey in mail/email.

Please answer 1-3. If symptoms of Bell's Palsy have returned or gotten worse, or the HB- Parent Perception is >2, please ask questions 4-9.

If symptoms have not returned and HB- Parent Perception =1, skip to appropriate participant questionnaire.

1 Date: / / (dd/mm/yyyy)

2 Do you feel the symptoms of Bell's Palsy have returned or gotten worse?

Yes No Unknown

3 **House Brackmann- Parent Perception.**

Please read the House Brackmann Lay form and choose which grade of facial severity you believe your child is (tick one only).

1 2 3 4 5 6

****The following questions are only for those patients whose symptoms have returned or gotten worse****

4 Since your follow up visit has your child reported any abnormal hearing

Yes No, *skip to qn. 5* Unknown

4.1 If yes, does the abnormal hearing continue

Yes No Unknown

4.2 If resolved, how long did it last for _____

5 Since your follow up visit has your any reduced or increased tear production

Yes No, *skip to qn 6* Unknown

5.1 If yes, which one

Reduced tear production Increased tear production Unknown

5.2 Does it continue?

Yes No Unknown

5.2 If resolved, how long did it last for _____

6 Does the your child report any altered taste since the follow up visit

Yes No, *skip to qn 7* Unknown

6.1 If yes, does the altered taste continue

Yes No Unknown

6.2 If resolved, how long did it last for _____

7 Have you taken your child to the hospital or doctors since the follow up visit *due to the Bell's palsy?*

Yes No Unknown

7.1 If yes, where did the patient visit: (*tick all that apply*)

GP
 Emergency Department
 Outpatient visit
 Hospital admission
 Other health service, describe _____

7.2 Please specify how many times they used each service _____

8 Over the past two months, has the patient had any days off from school/day care *due to Bell's Palsy?*

Yes No Unknown

8.1 If yes, please specify how many days _____

8.2 Who cared for the child during these days?

Parent, time off work
 Parent, no time off work required
 Unpaid informal carer
 Paid carer, specify how much this costs (per day) _____

If paid carer, did they receive the child care benefit:

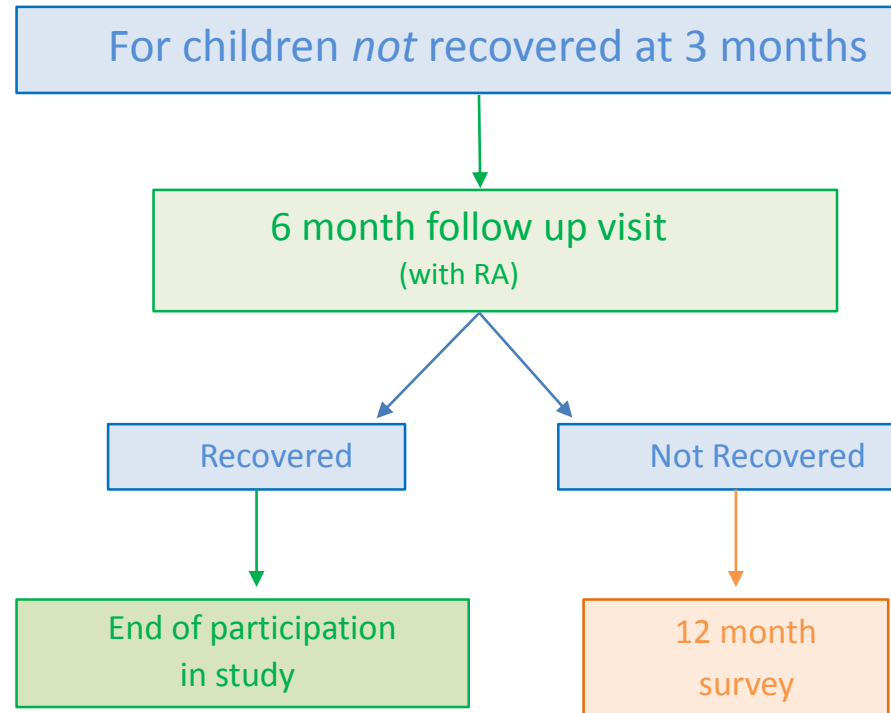
Yes No Unknown
 No care required (older children)

9 Did you seek any alternative therapies, eg. acupuncture, naturopath, etc?

Yes No Unknown

9.1 If yes, please specify _____

Time Points: *Not Recovered*



6 Month Follow Up

Paperwork and procedure is the same as 3 month follow up

CRF 8 used for non recovered patients at follow up visit

6 month surveys used for recovered patients

** Entered directly into RedCAP- CRF 8

12 Month Follow Up

Only for patients NOT recovered at 6 months

Will ask if they have recovered, and their recovery date.

No questionnaires, no study visits.

Ethics Amendment/Modification

RCH will submit a modification for the following

- List “Previous episode of Bell’s Palsy” as an exclusion criteria
- Submit all letters and surveys to HREC for review