Title	**Implementation and evaluation of a post-diagnostic announcement protocol at the Neuroretinal Disease Reference Center RefeRet, Quinze-Vingts Hospital.**
Acronyme	**RP-DIAG**
Principal Investigator	Pr Isabelle AUDO, CRMR
Sponsor	Quinze-Vingts National Vision Hospital (HNV des 15-20)
Study Justification	Retinitis pigmentosa (RP), the main genetic retinal dystrophy, affects approximately 1 in 4,000 people and is characterized by progressive vision loss. Receiving the diagnosis is often challenging: the long medical journey and lack of clear guidance increase anxiety, sometimes leading to a break in follow-up care. Unlike in oncology, there are no established post-diagnosis recommendations in this field. The current process at the Quinze-Vingts National Vision Hospital is limited to a consultation with the ophthalmologist, without formal coordination of psychological or nurse support. The **RP-DIAG** study aims to structure post-diagnosis follow-up (nurse and psychological support) and to evaluate its feasibility, impact, and potential for long-term implementation and adaptation in other rare disease centers.
Study Objectives	1. To evaluate a new post-diagnostic paramedical support pathway (nurse and psychological support) in order to improve care for patients with retinitis pigmentosa (RP). 2. To collect data on patients' psychological experience after diagnosis using the Hospital Anxiety and Depression Scale (HADS). 3. To assess the feasibility of generalizing the support pathway, including the workload for clinical teams, using the RETEX questionnaire, and to provide the basis for a standardized, sustainable post-diagnostic protocol that could potentially be reproduced in other ophthalmology rare disease centers.
Study Category and Type	Pilot study, RIPH2 category. Randomized, prospective, longitudinal, monocentric comparative study.
Evaluation Criteria and Outcome Measures	1 . **Patient-perceived satisfaction:** Measured using the PREM (Patient-Reported Experience Measure) questionnaire, comparing: – An experimental group receiving the structured nurse/psychological follow-up – A control group receiving usual care Measurement will be performed at 12 months. 2. **Psychological impact: Change in HADS (Hospital Anxiety and Depression Scale) scores in the experimental group at 15 days, 6 months, and 12 months.** 3. **Paramedical team feedback:** Collected via an observation log (RETEX questionnaire) to identify difficulties (organizational, logistical, interpersonal) and qualitatively and quantitatively evaluate the benefits of the intervention.
Inclusion Criteria	- Diagnosed with retinitis pigmentosa and receiving care at the Rare Disease Reference Center (CRMR), with diagnosis disclosure occurring after the project's initiation. - Aged between 18 and 65 years. - Male or female. - French-speaking. - Has a valid telephone number. - Resident of France.
Exclusion Criteria	- Individuals enrolled in a therapeutic clinical trial (for 12 months) - Individuals deprived of liberty by judicial or administrative decision (art. L1121-6 of the French Public Health Code) - Adults under legal protection measures or unable to provide consent (art. L1121-8 of the French Public Health Code) - Individuals with other medical conditions or taking treatments likely to interfere with study assessments - Participants unable to attend all study visits

<table>
<tr><td></td><td>- Pregnant, postpartum, or breastfeeding women (according to art. L1121-5 of the French Public Health Code).</td></tr>
<tr><td>Criteria for early withdrawal or study discontinuation</td><td>- Occurrence of other medical conditions or treatments which could interfere with the planned assessments of the study;
- A participant may decide at any time to withdraw from the study;
- A participant may also be withdrawn from the study by the investigator.</td></tr>
<tr><td>Constraints and Risks</td><td>This pilot study does not present any foreseeable medical risks.</td></tr>
<tr><td>Population</td><td>Target population: Adult patients diagnosed with retinitis pigmentosa (RP) who meet the inclusion criteria – first encounter with the name of their condition. Sample: 80 patients (40 in the experimental group, 40 in the control group). Randomization: Performed using the RedCAP software.</td></tr>
<tr><td>Study Procedure</td><td>Experimental Group (n=40)
1. Visit 1 (Diagnosis Announcement): Ophthalmologist consultation; project information; optional initial discussion with the nurse.
2. Consent Collection
3. Visit 2 (Day 15): Nurse consultation (in-person or by phone, ~1 hour) to explain the disease and procedures, and assess emotional state (HADS-1).
4. Visit 3 (6 months): Nurse consultation (HADS-2); psychologist consultation offered.
5. Visit 4 (12 months): Ophthalmology consultation; nurse consultation (HADS-3); PREM questionnaire to assess patient satisfaction.
Control Group (n=40)
• Usual care: Diagnosis consultation followed by a 12-month follow-up visit. At the 12-month visit, the patient completes the PREM questionnaire. No systematic nurse or psychological follow-up between diagnosis and the 12-month visit, unless requested by the patient.
Visit Schedule Summary
<table>
<tr><th>Visits</th><th>Day 0 (Announcement)</th><th>Day 15 (V1)</th><th>6 Months (V2)</th><th>12 Months (V3)</th></tr>
<tr><td>Informed Consent</td><td colspan="2">X</td><td>-</td><td>-</td></tr>
<tr><td>Control Group (Usual Care)</td><td>PREM</td><td>-</td><td>-</td><td>PREM</td></tr>
<tr><td>Experimental Group (Enhanced Support)</td><td>HADS</td><td>HADS</td><td>HADS + Psychologist</td><td>HADS + PREM</td></tr>
</table></td></tr>
<tr><td>Planned Study Timeline</td><td>Expected study start date: September 2025
Participant involvement duration: 12 months
Visit frequency: As detailed in the visit schedule above
Expected inclusion period: 10 months (approximately 8 patients enrolled per month)
Total study duration: 24 months</td></tr>
<tr><td>Source of Funding</td><td>The project is funded by the APRESO program of the GIRCI.</td></tr>
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